(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

§ 886.5928 Soft (hydrophilic) contact lens care products.

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: ''Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.''

[62 FR 30988, June 6, 1997]

§ 886.5933 [Reserved]

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888.3535 Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.
888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.
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888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.
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888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.
888.3650 Shoulder joint metal/polymer nonconstrained cemented prosthesis.
888.3660 Shoulder joint metal/polymer semiconstrained cemented prosthesis.
888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.
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888.3770 Wrist joint carpal trapezium polymer prosthesis.
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888.5940 Cast component.
888.5960 Cast removal instrument.
888.5980 Manual cast application and removal instrument.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

SOURCE: 52 FR 33702, Sept. 4, 1987, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 888 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 888.1 Scope.

(a) This part sets forth the classification of orthopedic devices intended for

human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, an orthopedic device that has two or more types of uses (e.g., used both as a diagnostic device and as a surgical device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*.

[52 FR 33702, Sept. 4, 1987, as amended at 68 FR 14137, Mar. 24, 2003; 78 FR 18233, Mar. 26, 2013]

§ 888.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraphs (b) and (c) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a ''new'' device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

(c) A device identified in a regulation in this part that is classified into class III and that is subject to the transitional provisions of section 520(1) of the act is automatically classified by statute into class III and must have an approval under section 515 of the act before being commercially distributed. Accordingly, the regulation for such a class III transitional device states that as of the enactment date of the amendments, May 28, 1976, the device must

have an approval under section 515 of the act before commercial distribution.

§ 888.5 Resurfacing technique.

Because of resurfacing techniques, certain joint prostheses require far less bone resection than other devices intended to repair or replace the same joint. The amount of bone resection may or may not affect the safety and effectiveness of the implantation of the prosthesis. When a resurfacing technique is used, the name of the prosthesis includes this information.

§ 888.6 Degree of constraint.

Certain joint prostheses provide more constraint of joint movement than others. FDA believes that the degree of constraint is an important factor affecting the safety and effectiveness of orthopedic prostheses. FDA is defining the following standard terms for categorizing the degree of constraint.

(a) A ''constrained'' joint prosthesis is used for joint replacement and prevents dislocation of the prosthesis in more than one anatomic plane and consists of either a single, flexible, across-the-joint component or more than one component linked together or affined.

(b) A ''semi-constrained'' joint prosthesis is used for partial or total joint replacement and limits translation and rotation of the prosthesis in one or more planes via the geometry of its articulating surfaces. It has no across-the-joint linkage.

(c) A ''non-constrained'' joint prosthesis is used for partial or total joint replacement and restricts minimally prosthesis movement in one or more planes. Its components have no across-the-joint linkage.

§ 888.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I or II device is only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, only to the extent that misdiagnosis as a result of using the device would not be associated with high morbidity or mortality. Accordingly, manufacturers of any commercially distributed class I or II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only;

(b) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(c) The device is an in vitro device that is intended:

(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;

(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(4) For assessing the risk of cardiovascular diseases;

(5) For use in diabetes management;

(6) For identifying or inferring the identity of a microorganism directly from clinical material;

(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays

when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(8) For noninvasive testing as defined in § 812.3(k) of this chapter; and

(9) For near patient testing (point of care).

[65 FR 2321, Jan. 14, 2000]

Subpart B—Diagnostic Devices

§ 888.1100 Arthroscope.

(a) *Identification.* An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for the following manual arthroscopic instruments: cannulas, currettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knotpushers, suture punches, switching rods, and trocars. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38815, July 25, 2001]

§ 888.1240 AC-powered dynamometer.

(a) *Identification.* An AC-powered dynamometer is an AC-powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient's hand.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

[52 FR 33702, Sept. 4, 1987, as amended at 84 FR 71818, Dec. 30, 2019]

§ 888.1250 Nonpowered dynamometer.

(a) *Identification.* A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient's hand.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

§ 888.1500 Goniometer.

(a) *Identification.* A goniometer is an AC-powered or battery powered device intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint.

(b) *Classification.* (1) Class I (general controls) for a goniometer that does not use electrode lead wires and patient cables. This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 888.9.

(2) Class II (special controls) for a goniometer that uses electrode lead wires and patient cables. The special controls consist of:

(i) The performance standard under part 898 of this chapter, and

(ii) The guidance entitled ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 888.9.

[65 FR 19319, Apr. 11, 2000]

§ 888.1520 Nonpowered goniometer.

(a) *Identification.* A nonpowered goniometer is a mechanical device intended for medical purposes to measure the range of motion of joints.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§ 888.1600 Bone indentation device.

(a) *Identification.* A bone indentation device is a device that measures resistance to indentation in bone.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) In vivo performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must evaluate the risk of bone fracture, soft tissue damage, pain, discomfort, bruising, or bleeding.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including an evaluation of the accuracy and precision of the device with respect to resistance to bone indentation.

(3) Human factors testing must demonstrate that the intended user(s) can correctly use the device, based on the instructions for use.

(4) The patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance testing must demonstrate:

(i) The sterility of the patient-contacting components of the device; and

(ii) Validation of reprocessing instructions for any reusable components of the device.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility and device functionality over the identified shelf life.

(7) Software verification, validation, and hazard analysis must be performed.

(8) Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(9) Labeling must include:

(i) Instructions for use;

(ii) Validated methods and instructions for reprocessing of any reusable components;

(iii) A shelf life for any sterile components;

(iv) Information regarding limitations of the clinical significance of the device output; and

(v) A detailed summary of the accuracy and precision of the device.

[88 FR 755, Jan. 5, 2023]

Subpart C [Reserved]

Subpart D—Prosthetic Devices

§ 888.3000 Bone cap.

(a) *Identification.* A bone cap is a mushroom-shaped device intended to be implanted made of either silicone elastomer or ultra-high molecular weight polyethylene. It is used to cover the severed end of a long bone, such as the humerus or tibia, to control bone overgrowth in juvenile amputees.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38815, July 25, 2001]

§ 888.3010 Bone fixation cerclage.

(a) *Identification.* A bone fixation cerclage is a device intended to be implanted that is made of alloys, such as cobalt-chromium-molybdenum, and that consists of a metallic ribbon or flat sheet or a wire. The device is wrapped around the shaft of a long bone, anchored to the bone with wire or screws, and used in the fixation of fractures.

(b) *Classification.* Class II.

§ 888.3015 Bone heterograft.

(a) *Identification.* Bone heterograft is a device intended to be implanted that is made from mature (adult) bovine bones and used to replace human bone following surgery in the cervical region of the spinal column.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 888.3.

§ 888.3020 Intramedullary fixation rod.

(a) *Identification.* An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures.

(b) *Classification.* Class II.

§ 888.3023 In vivo cured intramedullary fixation rod.

(a) *Identification.* An in vivo cured intramedullary fixation rod is a prescription implanted device consisting of a balloon that is inserted into the medullary canal of long bones for the fixation of fractures. The balloon is infused with, and completely encapsulates, a liquid monomer that is exposed to a curing agent which polymerizes the monomer within the balloon creating a hardened rigid structure.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Mechanical testing must be conducted on the final device to assess burst, abrasion, bending, and torsion in static and dynamic conditions.

(ii) Mechanical testing must demonstrate the integrity of the balloon including testing for leaks, ruptures, and release of cured/uncured material.

(iii) Performance testing must demonstrate that the device can be inserted and removed.

(iv) Performance testing must demonstrate the ability, in the event of a leak, to remove the uncured material from its in vivo location.

(v) Performance testing must demonstrate the reliability and accuracy of the curing method used.

(vi) Thermal safety testing must be conducted to evaluate the temperature rise during curing.

(2) Electrical safety, electromagnetic compatibility (EMC) testing, and electromagnetic interference (EMI) testing must be conducted for all electrical components.

(3) All patient-contacting components must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility and pyrogenicity of patient contacting components of the device that are provided sterile.

(5) Performance data must validate the reprocessing instructions for any reusable components or instruments.

(6) Performance data must support the shelf life of the system by demonstrating continued sterility, package integrity, and system functionality over the established shelf life.

(7) Technological characterization of the device must include materials, curing agents, and a description of the operating principles of the device, including the delivery system and devices which initiate the curing process.

(8) Labeling must include the following:

(i) A detailed summary of the device technical parameters.

(ii) Information describing all materials of the device.

(iii) Information describing how to perform the procedure and use the device, including the delivery system and devices which initiate the curing process, as well as how to remove the device and any uncured materials.

(iv) A shelf life.

(v) Validated methods and instructions for reprocessing any reusable components or instruments.

[83 FR 26759, June 8, 2018]

§ 888.3025 Passive tendon prosthesis.

(a) *Identification.* A passive tendon prosthesis is a device intended to be implanted made of silicon elastomer or a polyester reinforced medical grade silicone elastomer intended for use in the surgical reconstruction of a flexor tendon of the hand. The device is implanted for a period of 2 to 6 months to aid growth of a new tendon sheath. The device is not intended as a permanent implant nor to function as a replacement for the ligament or tendon nor to function as a scaffold for soft tissue ingrowth.

(b) *Classification.* Class II.

§ 888.3027 Polymethylmethacrylate (PMMA) bone cement.

(a) *Identification.* Polymethylmethacrylate (PMMA) bone cement is a device intended to be implanted that is made from methylmethacrylate, polymethylmethacrylate, esters of methacrylic acid, or copolymers containing polymethylmethacrylate and polystyrene. The device is intended for use in arthroplastic procedures of the

hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement.''

[67 FR 46855, July 17, 2002]

§ 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

(a) *Identification.* Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 888.3040 Smooth or threaded metallic bone fixation fastener.

(a) *Identification.* A smooth or threaded metallic bone fixation fastener is a device intended to be implanted that consists of a stiff wire segment or rod made of alloys, such as cobalt-chromium-molybdenum and stainless steel, and that may be smooth on the outside, fully or partially threaded, straight or U-shaped; and may be either blunt pointed, sharp pointed, or have a formed, slotted head on the end. It may be used for fixation of bone fractures, for bone reconstructions, as a guide pin for insertion of other implants, or it may be implanted through the skin so that a pulling force (traction) may be applied to the skeletal system.

(b) *Classification.* Class II.

§ 888.3043 Screw sleeve bone fixation device.

(a) *Identification.* A screw sleeve bone fixation device is intended to be implanted in conjunction with a nonresorbable, metallic bone screw where the screw has lost purchase due to loosening, backout, or breakage. The device fits between the screw threads and surrounding bone and provides increased surface area to create an interference fit to restore stability of the implant construct.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) In vivo performance testing under anticipated conditions of use must demonstrate:

(i) The device provides sufficient stability to allow for fracture healing; and

(ii) A lack of adverse biologic response to the implant through histopathological and histomorphometric assessment.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must:

(i) Assess the stability of the device in a rescue screw scenario;

(ii) Demonstrate that the device can be inserted and removed without damage to the implant or associated hardware;

(iii) Demonstrate the device can withstand dynamic loading without device failure; and

(iv) Characterize wear particle generation.

(3) The device must be demonstrated to be biocompatible.

(4) The device must be demonstrated to be non-pyrogenic.

(5) Performance data must demonstrate the sterility of the device.

(6) Performance data must support the labeled shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the established shelf life.

(7) Labeling must include:

(i) A detailed summary of the device technical parameters;

(ii) Information describing all materials of the device;

(iii) Instructions for use, including device removal; and

(iv) A shelf life.

[87 FR 11294, Mar. 1, 2022]

§ 888.3044 Resorbable implant for anterior cruciate ligament (ACL) repair.

(a) *Identification.* A resorbable implant for anterior cruciate ligament (ACL) repair is a degradable material that allows for healing of a torn ACL that is biomechanically stabilized by traditional suturing procedures. The device is intended to protect the biological healing process from the surrounding intraarticular environment and not intended to replace biomechanical fixation via suturing. This classification includes devices that bridge or surround the torn ends of a ruptured ACL.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Post-operative evaluation of knee pain and function; and

(ii) Durability as assessed by re-tear or re-operation rate.

(2) Animal performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Device performance characteristics, including resorption and ligament healing at repair site; and

(ii) Adverse effects as assessed by gross necropsy and histopathology.

(3) Non-clinical testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Characterization of materials, including chemical composition, resorption profile, and mechanical properties; and

(ii) Simulated use testing, including device preparation, device handling, compatibility with other ACL repair instrumentation, and user interface.

(4) The device must be demonstrated to be biocompatible.

(5) Performance data must demonstrate the device to be sterile and non-pyrogenic.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(7) Labeling must include the following:

(i) Identification of device materials and specifications;

(ii) A summary of the clinical performance testing conducted with the device;

(iii) Instructions for use, including compatibility with other ACL repair instrumentation or devices;

(iv) Warnings regarding post-operative rehabilitation requirements; and

(v) A shelf life.

[87 FR 80041, Dec. 29, 2022]

§ 888.3045 Resorbable calcium salt bone void filler device.

(a) *Identification.* A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA.'' See § 888.1(e) of this chapter for the availability of this guidance.

[68 FR 32636, June 2, 2003]

§ 888.3050 Spinal interlaminal fixation orthosis.

(a) *Identification.* A spinal interlaminal fixation orthosis is a device intended to be implanted made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily

in the treatment of scoliosis (a lateral curvature of the spine), but it also may be used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

(b) *Classification*. Class II.

§ 888.3060 Spinal intervertebral body fixation orthosis.

(a) *Identification*. A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct ''sway back,'' scoliosis (lateral curvature of the spine), or other conditions.

(b) *Classification*. Class II.

§ 888.3070 Thoracolumbosacral pedicle screw system.

(a) *Identification*. (1) Rigid pedicle screw systems are comprised of multiple components, made from a variety of materials that allow the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of screws, longitudinal members (*e.g.*, plates, rods including dual diameter rods, plate/rod combinations), transverse or cross connectors, and interconnection mechanisms (*e.g.*, rod-to-rod connectors, offset connectors).

(2) Semi-rigid systems are defined as systems that contain one or more of the following features (including but not limited to): Non-uniform longitudinal elements, or features that allow more motion or flexibility compared to rigid systems.

(b) *Classification*. (1) Class II (special controls), when intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). These pedicle screw spinal systems must comply with the following special controls:

(i) Compliance with material standards;

(ii) Compliance with mechanical testing standards;

(iii) Compliance with biocompatibility standards; and

(iv) Labeling that contains these two statements in addition to other appropriate labeling information:

''Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.''

''Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.''

(2) Class II (special controls), when a rigid pedicle screw system is intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5–S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment. These pedicle screw systems must comply with the following special controls:

(i) The design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(ii) Non-clinical performance testing must demonstrate the mechanical function and durability of the implant.

(iii) Device components must be demonstrated to be biocompatible.

(iv) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.

(v) Labeling must include the following:

(A) A clear description of the technological features of the device including identification of device materials and the principles of device operation;

(B) Intended use and indications for use, including levels of fixation;

(C) Identification of magnetic resonance (MR) compatibility status;

(D) Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user; and

(E) Detailed instructions of each surgical step, including device removal.

(3) Class II (special controls), when a semi-rigid system is intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion for any indication. In addition to complying with the special controls in paragraphs (b)(2)(i) through (v) of this section, these pedicle screw systems must comply with the following special controls:

(i) Demonstration that clinical performance characteristics of the device support the intended use of the product, including assessment of fusion compared to a clinically acceptable fusion rate.

(ii) Semi-rigid systems marketed prior to the effective date of this reclassification must submit an amendment to their previously cleared premarket notification (510(k)) demonstrating compliance with the special controls in paragraphs (b)(2)(i) through (v) and paragraph (b)(3)(i) of this section.

[66 FR 28053, May 22, 2001, as amended at 81 FR 96373, Dec. 30, 2016]

§ 888.3075 Posterior cervical screw system.

(a) *Identification.* Posterior cervical screw systems are comprised of multiple, interconnecting components, made from a variety of materials that allow an implant system to be built from the occiput to the upper thoracic spine to fit the patient's anatomical and physiological requirements, as determined by preoperative cross-sectional imaging. Such a spinal assembly consists of a combination of bone anchors via screws (*i.e.*, occipital screws, cervical lateral mass screws, cervical pedicle screws, C2 pars screws, C2 translaminar screws, C2 transarticular screws), longitudinal members (*e.g.*, plates, rods, including dual diameter rods, plate/rod combinations), transverse or cross connectors, interconnection mechanisms (*e.g.*, rod-to-rod connectors, offset connectors), and closure mechanisms (*e.g.*, set screws, nuts). Posterior cervical screw systems are rigidly fixed devices that do not contain dynamic features, including but not limited to: non-uniform longitudinal elements or features that allow more motion or flexibility compared to rigid systems.

Posterior cervical screw systems are intended to provide immobilization and stabilization of spinal segments in patients as an adjunct to fusion for acute and chronic instabilities of the cervical spine and/or craniocervical junction and/or cervicothoracic junction such as: (1) Traumatic spinal fractures and/or traumatic dislocations; (2) deformities; (3) instabilities; (4) failed previous fusions (*e.g.*, pseudarthrosis); (5) tumors; (6) inflammatory disorders; (7) spinal degeneration, including neck and/or arm pain of discogenic origin as confirmed by imaging studies (radiographs, CT, MRI); (8) degeneration of the facets with instability; and (9) reconstruction following decompression to treat radiculopathy and/or myelopathy. These systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

(b) *Classification.* Class II (special controls). The special controls for posterior cervical screw systems are:

(1) The design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(2) Nonclinical performance testing must demonstrate the mechanical function and durability of the implant.

(3) Device components must be demonstrated to be biocompatible.

(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.

(5) Labeling must include the following:

(i) A clear description of the technological features of the device including identification of device materials and the principles of device operation;

(ii) Intended use and indications for use including levels of fixation;

(iii) Device specific warnings, precautions, and contraindications that include the following statements:

(A) ''Precaution: Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (*e.g.,* CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.''

(B) ''Precaution: Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.''

(iv) Identification of magnetic resonance (MR) compatibility status;

(v) Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user, and;

(vi) Detailed instructions of each surgical step, including device removal.

[84 FR 12092, Apr. 1, 2019]

§ 888.3080 Intervertebral body fusion device.

(a) *Identification.* An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) *Classification.* (1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.'' See § 888.1(e) for the availability of this guidance document.

(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[72 FR 32172, June 12, 2007]

§ 888.3083 Spinal spheres for use in intervertebral fusion procedures.

(a) *Identification.* A spinal sphere device is an implanted, solid, spherical, prescription device manufactured from metallic or polymeric materials. The device is inserted into the intervertebral body space of the lumbar spine to provide stabilization and to help promote intervertebral body fusion. The device is to be used with bone graft material.

(b) *Classification.* Class III.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 30, 2025, for any spinal sphere

for use in intervertebral fusion procedures as identified in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has, on or before October 30, 2025, been found to be substantially equivalent to any spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section, that was in commercial distribution before May 28, 1976. Any other spinal sphere device for use in intervertebral fusion procedures identified in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[88 FR 18990, 18993, Mar. 30, 2023]

§ 888.3085 Intervertebral body graft containment device.

(a) *Identification.* An intervertebral body graft containment device is a non-rigid, implanted spinal device that is designed to contain bone graft within its internal cavity. The device is inserted into the intervertebral body space of the spine and is intended as an adjunct to intervertebral body fusion.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must include an assessment of any adverse events observed during clinical use, as well as intervertebral body fusion, and compare this to a clinically acceptable fusion rate.

(2) Non-clinical performance testing must demonstrate the mechanical function and durability of the implant, as well as the ability of the device to be inserted, deployed, and filled with bone graft consistently.

(3) Device must be demonstrated to be biocompatible.

(4) Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components, and device-specific instruments.

(5) Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(6) Labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device including identification of device materials, compatible components in the fusion construct, and the principles of device operation;

(ii) Intended use and indications for use, including levels of fixation;

(iii) Identification of magnetic resonance (MR) compatibility status;

(iv) Cleaning and sterilization instructions for devices and instruments that are provided nonsterile to the end user; and

(v) Detailed instructions of each surgical step, including device removal.

[89 FR 71158, Sept. 3, 2024]

§ 888.3090 Intraoperative orthopedic strain sensor.

(a) *Identification.* A strain sensor device is an adjunct tool intended to measure strain on an orthopedic implant in the intraoperative setting only. The device is not intended to provide diagnostic information or influence clinical decision making.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance testing must be conducted:

(i) Mechanical testing to evaluate the effect of the device on the mechanical performance of the implant and to characterize the mechanical limits of the components used with the implant; and

(ii) Accuracy and repeatability testing of strain measurements.

(2) Usability testing must evaluate the effect of the device on the performance of the surgical procedure.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must support the sterility and shelf life of the patient-contacting components of the device.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Performance data must validate the reprocessing instructions for reusable components of the device.

(7) Performance data must be provided to demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.

(8) Labeling must include the following:

(i) A shelf life;

(ii) Instructions for use;

(iii) Reprocessing instructions for any reusable components; and

(iv) A statement that the device is not intended to provide diagnostic information or influence clinical decision making.

[86 FR 68405, Dec. 2, 2021]

§ 888.3100 Ankle joint metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/composite semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation: in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component fabricated from ultra-high molecular weight polyethylene with carbon fibers composite, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces and has no linkage across-the-joint. This generic type of device includes prostheses that have a talar resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a tibial resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3120 Ankle joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* An ankle joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace an ankle joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a tibial component made of alloys, such as cobalt-chromium-molybdenum, and a talar component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996, been found to be substantially equivalent to an ankle joint metal/polymer non-constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other ankle joint metal/polymer non-constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50709, Sept. 27, 1996]

§ 888.3150 Elbow joint metal/polymer constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. It is made of alloys, such as cobalt-chromium-molybdenum, or of these alloys and of an ultra-high molecular weight polyethylene bushing. The device prevents dislocation in more than one

anatomic plane and consists of two components that are linked together. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(iii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iv) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,''

(v) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,''

(2) International Organization for Standardization's (ISO):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,''

(ii) ISO 5832–4:1996 ''Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,''

(iii) ISO 5832–12:1996 ''Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,''

(iv) ISO 5833:1992 ''Implants for Surgery—Acrylic Resin Cements,''

(v) ISO 5834–2:1998 ''Implants for Surgery—Ultra High Molecular Weight Polyethylene—Part 2: Moulded Forms,''

(vi) ISO 6018:1987 ''Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,''

(vii) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(viii) ISO 14630:1997 ''Non-active Surgical Implants—General Requirements,''

(3) American Society for Testing and Materials':

(i) F 75–92 ''Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,''

(ii) F 648–98 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(iii) F 799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iv) F 981–93 ''Practice for Assessment of Compatibility of Biomaterials (Nonporous) for Surgical Implant with Respect to Effect of Material on Muscle and Bone,''

(v) F 1044–95 ''Test Method for Shear Testing of Porous Metal Coatings,''

(vi) F 1108–97 ''Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,''

(vii) F 1147–95 ''Test Method for Tension Testing of Porous Metal Coatings,'' and

(viii) F 1537–94 ''Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.''

[65 FR 17147, Mar. 31, 2000]

§ 888.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* An elbow joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace an elbow joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a radial resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis.

(a) *Identification.* An elbow joint radial (hemi-elbow) polymer prosthesis is a device intended to be implanted made of medical grade silicone elastomer used to replace the proximal end of the radius.

(b) *Classification.* Class II.

§ 888.3180 Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis.

(a) *Identification.* An elbow joint humeral (hemi-elbow) metallic uncemented prosthesis is a device intended to be implanted made of alloys, such as cobalt-chromium-molybdenum, that is used to replace the distal end of the humerus formed by the trochlea humeri and the capitulum humeri. The generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any elbow joint humeral (hemi-elbow) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to an elbow joint humeral (hemi-elbow) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other elbow joint humeral (hemi-elbow) metallic uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50709, Sept. 27, 1996]

§ 888.3200 Finger joint metal/metal constrained uncemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained uncemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane and consists of two components which are linked together. This generic type of device includes prostheses made of alloys, such as cobalt-chromium-molybdenum, or protheses made from alloys and ultra-high molecular weight polyethylene. This generic type of device is limited to prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any finger joint metal/metal constrained uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a finger joint metal/metal constrained uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/metal constrained uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50709, Sept. 27, 1996]

§ 888.3210 Finger joint metal/metal constrained cemented prosthesis.

(a) *Identification.* A finger joint metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal (finger) joint. This device prevents dislocation in more than one anatomic plane and has components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any finger joint metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a finger joint metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/metal constrained cemented prosthesis shall have an approved PMA or a declared

completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50709, Sept. 27, 1996]

§ 888.3220 Finger joint metal/polymer constrained cemented prosthesis.

(a) *Identification.* A finger joint metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. The device prevents dislocation in more than one anatomic plane, and consists of two components which are linked together. This generic type of device includes prostheses that are made of alloys, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any finger joint metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a finger joint metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other finger joint metal/polymer constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50709, Sept. 27, 1996]

§ 888.3230 Finger joint polymer constrained prosthesis.

(a) *Identification.* A finger joint polymer constrained prosthesis is a device intended to be implanted to replace a metacarpophalangeal or proximal interphalangeal (finger) joint. This generic type of device includes prostheses that consist of a single flexible across-the-joint component made from either a silicone elastomer or a combination pf polypropylene and polyester material. The flexible across-the-joint component may be covered with a silicone rubber sleeve.

(b) *Classification.* Class II.

§ 888.3300 Hip joint metal constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have components made of alloys, such as cobalt-chromium-molybdenum, and is intended for use with or without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint metal constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint metal constrained cemented or uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal constrained cemented or uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50709, Sept. 27, 1996]

§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

(a) *Identification.* A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an

acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027).

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.''

[67 FR 21173, Apr. 30, 2002]

§ 888.3320 Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before May 18, 2016, for any hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component that was in commercial distribution before May 28, 1976, or that has, on or before May 18, 2016, been found to be substantially equivalent to a hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component that was in commercial distribution before May 28, 1976. Any other hip joint metal/metal semi-constrained prosthesis with a cemented acetabular component shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 81 FR 8149, Feb. 18, 2016]

§ 888.3330 Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

(a) *Identification.* A hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis is a two-part device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral and an acetabular component, both made of alloys, such as cobalt-chromium-molybdenum. The femoral component is intended to be fixed with bone cement. The acetabular component is intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before May 18, 2016, for any hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component that was in commercial distribution before May 28, 1976, or that has, on or before May 18, 2016, been found to be substantially equivalent to a hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component that was in commercial distribution before May 28, 1976. Any other hip joint metal/metal semi-constrained prosthesis with an uncemented acetabular component shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 81 FR 8149, Feb. 18, 2016]

§ 888.3340 Hip joint metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* A hip joint metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace a hip joint.

The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high molecular weight polyethylene with carbon fibers composite. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular resurfacing component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

(a) *Identification.* A hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis is a device intended to be implanted to replace a hip joint. This device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. The two-part femoral component consists of a femoral stem made of alloys to be fixed in the intramedullary canal of the femur by impaction with or without use of bone cement. The proximal end of the femoral stem is tapered with a surface that ensures positive locking with the spherical ceramic (aluminium oxide, $A1_20_3$) head of the femoral component. The acetabular component is made of ultra-high molecular weight polyethylene or ultra-high molecular weight polyethylene reinforced with nonporous metal alloys, and used with or without bone cement.

(b) *Classification.* Class II.

[54 FR 48239, Nov. 22, 1989; 54 FR 51342, Dec. 14, 1989]

§ 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

(a) *Identification.* A hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device has a femoral component made of a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy or a titanium-aluminum-vanadium (Ti-6Al-4V) alloy and an acetabular component composed of an ultra-high molecular weight polyethylene articulating bearing surface fixed in a metal shell made of Co-Cr-Mo or Ti-6Al-4V. The femoral stem and acetabular shell have a porous coating made of, in the case of Co-Cr-Mo substrates, beads of the same alloy, and in the case of Ti-6Al-4V substrates, fibers of commercially pure titanium or Ti-6Al-4V alloy. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. The generic type of device has a design to achieve biological fixation to bone without the use of bone cement.

(b) *Classification.* Class II.

[58 FR 3228, Jan. 8, 1993]

§ 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device includes designs which are intended to be

fixed to the bone with bone cement (§ 888.3027) as well as designs which have large window-like holes in the stem of the device and which are intended for use without bone cement. However, in these latter designs, fixation of the device is not achieved by means of bone ingrowth.

(b) *Classification.* Class II.

§ 888.3370 Hip joint (hemi-hip) acetabular metal cemented prosthesis.

(a) *Identification.* A hip joint (hemi-hip) acetabular metal cemented prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have an acetabular component made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint (hemi-hip) acetabular metal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal (hemi-hip) acetabular metal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996]

§ 888.3380 Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that consist of a metallic stem made of alloys, such as cobalt-chromium-molybdenum, with an integrated cylindrical trunnion bearing at the upper end of the stem that fits into a recess in the head of the device. The head of the device is made of polyacetal (polyoxymethylene) and it is covered by a metallic alloy, such as cobalt-chromium-molybdenum. The trunnion bearing allows the head of the device to rotate on its stem. The prosthesis is intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996]

§ 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis is a two-part device intended to be implanted to replace the head and neck of the femur. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a snap-fit acetabular component made of an alloy, such as cobalt-chromium-molybdenum, and ultra-high molecular weight polyethylene. This generic type of device may be fixed to the bone with bone cement (§ 888.3027) or implanted by impaction.

(b) *Classification.* Class II.

§ 888.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis.

(a) *Identification.* A hip joint femoral (hemi-hip) metallic resurfacing prosthesis is a device intended to be implanted to replace a portion of the hip joint. This generic type of device includes prostheses that have a femoral resurfacing component made of alloys, such as cobalt-chromium-molybdenum.

(b) *Classification.* Class II.

§ 888.3410 Hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis.

(a) *Identification.* A hip joint metal/polymer or ceramic/polymer semi-constrained resurfacing cemented prosthesis is a two-part device intended to be implanted to replace the articulating surfaces of the hip while preserving the femoral head and neck. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device includes prostheses that consist of a femoral cap component made of a metal alloy, such as cobalt-chromium-molybdenum, or a ceramic material, that is placed over a surgically prepared femoral head, and an acetabular resurfacing polymer component. Both components are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before January 3, 2005, for any hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before January 3, 2005, been found to be substantially equivalent to a hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis that was in commercial distribution before May 28, 1976. Any other hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis must have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[69 FR 59134, Oct. 4, 2004]

§ 888.3480 Knee joint femorotibial metallic constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metallic constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. The only knee joint movement allowed by the device is in the sagittal plane. This generic type of device includes prostheses that have an intramedullary stem at both the proximal and distal locations. The upper and lower components may be joined either by a solid bolt or pin, an internally threaded bolt with locking screw, or a bolt retained by circlip. The components of the device are made of alloys, such as cobalt-chromium-molybdenum. The stems of the device may be perforated, but are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint femorotibial metallic constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint femorotibial metallic constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint femorotibial metallic constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996]

§ 888.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in

one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial condylar component or components made of ultra-high molecular weight polyethylene with carbon fibers composite and are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/composite semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component with the articulating surfaces made of ultra-high molecular weight polyethylene with carbon-fibers composite and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation or rotation in one or more planes and has components that are linked together or affined. This generic type of device includes prostheses composed of a ball-and-socket joint located between a stemmed femoral and a stemmed tibial component and a runner and track joint between each pair of femoral and tibial condyles. The ball-and-socket joint is composed of a ball at the head of a column rising from the stemmed tibial component. The ball, the column, the tibial plateau, and the stem for fixation of the tibial component are made of an alloy, such as cobalt-chromium-molybdenum. The ball of the tibial component is held within the socket of the femoral component by the femoral component's flat outer surface. The flat outer surface of the tibial component abuts both a reciprocal flat surface within the cavity of the femoral component and flanges on the femoral component designed to prevent distal displacement. The stem of the femoral component is made of an alloy, such as cobalt-chromium-molybdenum, but the socket of the component is made of ultra-high molecular weight polyethylene. The femoral component has metallic runners which align with the ultra-high molecular weight polyethylene tracks that press-fit into the metallic tibial component. The generic class also includes devices whose upper and lower components are linked with a solid bolt passing through a journal bearing of greater radius, permitting some rotation in the transverse plane, a minimal arc of abduction/adduction. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral condylar resurfacing component or components made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components made of ultra-high molecular weight polyethylene and are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint femorotibial metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component made of ultra-high molecular weight polyethylene and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3535 Knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.

(a) *Identification.* A knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surface. It has no linkage across-the-joint. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement. This identification includes fixed-bearing knee prostheses where the ultra-high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial baseplate.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance: ''Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.'' See § 888.1 for the availability of this guidance.

[68 FR 14137, Mar. 24, 2003]

§ 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis is a two-part device intended to be implanted to replace part of a knee joint in the treatment of primary patellofemoral arthritis or chondromalacia. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes a component made of alloys, such as cobalt-chromium-molybdenum or austenitic steel, for resurfacing the intercondylar groove (femoral sulcus) on the anterior aspect of the distal femur, and a patellar component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those devices intended for use with bone cement (§ 888.3027). The patellar component is designed to be implanted only with its femoral component.

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(iii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iv) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Applications for Orthopedic Devices,'' and

(v) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,'' and

(2) International Organization for Standardization's (ISO):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,''

(ii) ISO 5832–4:1996 ''Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,''

(iii) ISO 5832–12:1996 ''Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,''

(iv) ISO 5833:1992 ''Implants for Surgery—Acrylic Resin Cements,''

(v) ISO 5834–2:1998 ''Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,''

(vi) ISO 6018:1987 ''Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,''

(vii) ISO 7207–2:1998 ''Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 2: Articulating Surfaces Made of Metal, Ceramic and Plastic Materials,'' and

(viii) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(3) American Society for Testing and Materials':

(i) F 75–92 ''Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,''

(ii) F 648–98 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(iii) F 799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iv) F 1044–95 ''Test Method for Shear Testing of Porous Metal Coatings,''

(v) F 1108–97 ''Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,''

(vi) F 1147–95 ''Test Method for Tension Testing of Porous Metal Coatings,''

(vii) F 1537–94 ''Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants,'' and

(viii) F 1672–95 ''Specification for Resurfacing Patellar Prosthesis.''

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996; 65 FR 17147, Mar. 31, 2000]

§ 888.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component, a tibial component, a cylindrical bolt and accompanying locking hardware that are all made of alloys, such as cobalt-chromium-molybdenum, and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. The retropatellar surfacing component may be attached to the resected patella either with a metallic screw or bone cement. All stemmed metallic components within this generic type are intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996]

§ 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing

component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.

(a) *Identification.* A knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement. This identification includes fixed-bearing knee prostheses where the ultra high molecular weight polyethylene tibial bearing is rigidly secured to the metal tibial base plate.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance: ''Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA.'' See § 888.1 for the availability of this guidance.

[68 FR 14137, Mar. 24, 2003]

§ 888.3570 Knee joint femoral (hemi-knee) metallic uncemented prosthesis.

(a) *Identification.* A knee joint femoral (hemi-knee) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace part of a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that consist of a femoral component with or without protuberance(s) for the enhancement of fixation and is limited to those prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint femoral (hemi-knee) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint femoral (hemi-knee) metallic uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint femoral (hemi-knee) metallic uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50710, Sept. 27, 1996]

§ 888.3580 Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum, intended to be implanted to replace the retropatellar articular surface of the patellofemoral joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a retropatellar resurfacing component and an orthopedic screw to transfix the patellar remnant. This generic type of device is limited to those prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* (1) Class II when intended for treatment of degenerative and posttraumatic patellar arthritis.

(2) Class III when intended for uses other than treatment of degenerative and posttraumatic patellar arthritis.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis described in paragraph (b)(2) of this section that was in commercial

distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis that was in commercial distribution before May 28, 1976. Any other knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50711, Sept. 27, 1996]

§ 888.3590 Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis.

(a) *Identification.* A knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis is a device intended to be implanted to replace part of a knee joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This prosthesis is made of alloys, such as cobalt-chromium-molybdenum, and is intended to resurface one tibial condyle. The generic type of device is limited to those prostheses intended for use without bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3600 Implantable post-surgical kinematic measurement knee device.

(a) *Identification.* An implantable post-surgical kinematic measurement knee device is a device that provides objective kinematic data after total knee arthroplasty surgery. The kinematic data provided by the device are used as an adjunct to other physiological parameter measurement tools utilized during the course of patient monitoring and treatment post surgery.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following tests must be conducted:

(i) Mechanical testing must evaluate the mechanical function (mechanical fatigue, static mechanical strength) and durability of the implant.

(ii) Simulated use testing must evaluate the ability of the device to be sized, inserted, and sufficiently secured to any compatible components.

(iii) Testing must demonstrate the accuracy, reliability, and reproducibility of kinematic measurements.

(iv) Testing must demonstrate diagnostic and therapeutic ultrasound conditions for safe use.

(v) Testing must demonstrate that the device performs as intended under anticipated conditions of use demonstrating the following performance characteristics, if applicable:

(A) Magnetic pulse output testing;

(B) Magnetic and electrical field testing; and

(C) Testing of the safety features built into the device.

(vi) Testing must demonstrate hermeticity of any electronic component enclosures.

(2) Performance testing must evaluate the compatibility of the device in a magnetic resonance (MR) environment.

(3) Human factors testing must demonstrate that the intended user(s) can correctly use the device for its intended use, including for implantation and post-procedure data access.

(4) Performance data must demonstrate the sterility of the device implant and patient-contacting components.

(5) Performance data must validate the reprocessing instructions for the reusable components of the device.

(6) The patient-contacting components of the device must be demonstrated to be biocompatible.

(7) Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.

(8) Performance testing must demonstrate the electromagnetic compatibility/interference, (EMC/EMI), electrical safety, thermal safety, battery safety, and wireless performance of the device.

(9) Software verification, validation, and hazard analysis must be performed.

(10) The labeling must include the following:

(i) A shelf life;

(ii) Physician and patient instructions for use, including images that demonstrate how to interact with the device;

(iii) Detailed instruction of the surgical technique;

(iv) Hardware and software requirements for interacting with the device;

(v) A clear description of the technological features of the device including identification of the device materials, compatible components, and the principles of operation;

(vi) Identification of magnetic resonance (MR) compatibility status;

(vii) Validated methods and instructions for reprocessing of any reusable components; and

(viii) A statement regarding the limitations of the clinical significance of the kinematic data.

[88 FR 753, Jan. 5, 2023]

§ 888.3630 Resorbable shoulder spacer.

(a) *Identification.* A resorbable shoulder spacer is intended to act as a temporary spacer, creating a physical barrier between tissues in the shoulder, for the treatment of massive irreparable rotator cuff tears.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Evaluation of improvement of shoulder function and reduction of symptoms (*e.g.*, pain and function) for the indications for use; and

(ii) Evaluation of relevant adverse events.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use and include the following:

(i) Integrity testing of the device, including mechanical and chemical stability; and

(ii) Characterization of the device degradation profile.

(3) Animal performance testing must include evaluation of the following:

(i) Adverse effects, including gross necropsy and histopathology; and

(ii) Device degradation to verify in vitro versus in vivo degradation correlation.

(4) All patient-contacting components of the device must be demonstrated to be biocompatible.

(5) Performance data must support the sterility and pyrogenicity of the device components intended to be sterile.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

(7) Labeling must include the following:

(i) Instruction for use, including specific instructions regarding device selection and placement;

(ii) A detailed summary of the clinical performance testing with the device, including procedure- and device-related complications or adverse events; and

(iii) A shelf life.

[87 FR 981, Jan. 6, 2023]

§ 888.3640 Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/metal or metal/polymer constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid component made of this alloy or a combination of this alloy and ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that

has, on or before December 26, 1996 been found to be substantially equivalent to a shoulder joint metal/metal or metal/polymer constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint metal/metal or metal/polymer constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50711, Sept. 27, 1996]

§ 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer non-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits minimally (less than normal anatomic constraints) translation in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(iii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iv) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,'' and

(v) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,''

(2) International Organization for Standardization's (ISO):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-Aluminum 4-Vandium Alloy,''

(ii) ISO 5832–4:1996 ''Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy,''

(iii) ISO 5832–12:1996 ''Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy,''

(iv) ISO 5833:1992 ''Implants for Surgery—Acrylic Resin Cements,''

(v) ISO 5834–2:1998 ''Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,''

(vi) ISO 6018:1987 ''Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,'' and

(vii) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(3) American Society for Testing and Materials':

(i) F 75–92 ''Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,''

(ii) F 648–98 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(iii) F 799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iv) F 1044–95 ''Test Method for Shear Testing of Porous Metal Coatings,''

(v) F 1108–97 ''Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,''

(vi) F 1147–95 ''Test Method for Tension Testing of Porous Metal Coatings,''

(vii) F 1378–97 ''Specification for Shoulder Prosthesis,'' and

(viii) F 1537–94 ''Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.''

[52 FR 33702, Sept. 4, 1987, as amended at 65 FR 17148, Mar. 31, 2000]

§ 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral resurfacing component made of alloys, such as cobalt-chromium-molybdenum, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II. The special controls for this device are:

(1) FDA's:

(i) ''Use of International Standard ISO 10993 'Biological Evaluation of Medical Devices—Part I: Evaluation and Testing,' ''

(ii) ''510(k) Sterility Review Guidance of 2/12/90 (K90–1),''

(iii) ''Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement,''

(iv) ''Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices,'' and

(v) ''Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,''

(2) International Organization for Standardization's (ISO):

(i) ISO 5832–3:1996 ''Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-aluminum 4-vandium Alloy,''

(ii) ISO 5832–4:1996 ''Implants for Surgery—Metallic Materials—Part 4: Cobalt-chromium-molybdenum casting alloy,''

(iii) ISO 5832–12:1996 ''Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-chromium-molybdenum alloy,''

(iv) ISO 5833:1992 ''Implants for Surgery—Acrylic Resin Cements,''

(v) ISO 5834–2:1998 ''Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,''

(vi) ISO 6018:1987 ''Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling,'' and

(vii) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing,'' and

(3) American Society for Testing and Materials':

(i) F 75–92 ''Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,''

(ii) F 648–98 ''Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,''

(iii) F 799–96 ''Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,''

(iv) F 1044–95 ''Test Method for Shear Testing of Porous Metal Coatings,''

(v) F 1108–97 ''Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,''

(vi) F 1147–95 ''Test Method for Tension Testing of Porous Metal,''

(vii) F 1378–97 ''Standard Specification for Shoulder Prosthesis,'' and

(viii) F 1537–94 ''Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants.''

[52 FR 33702, Sept. 4, 1987, as amended at 65 FR 17148, Mar. 31, 2000]

§ 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits movement in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight bearing surface fixed in a metal

shell made of alloys such as Co-Cr-Mo and Ti-6Al-4V. The humeral component and glenoid backing have a porous coating made of, in the case of Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in the case of Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis.''

[66 FR 12737, Feb. 28, 2001]

§ 888.3680 Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis.

(a) *Identification.* A shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis is a device that has a glenoid (socket) component made of alloys, such as cobalt-chromium-molybdenum, or alloys with ultra-high molecular weight polyethylene and intended to be implanted to replace part of a shoulder joint. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis that was in commercial distribution before May 28, 1976. Any other shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50711, Sept. 27, 1996]

§ 888.3690 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

(a) *Identification.* A shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis is a device made of alloys, such as cobalt-chromium-molybdenum. It has an intramedullary stem and is intended to be implanted to replace the articular surface of the proximal end of the humerus and to be fixed without bone cement (§ 888.3027). This device is not intended for biological fixation.

(b) *Classification.* Class II.

§ 888.3720 Toe joint polymer constrained prosthesis.

(a) *Identification.* A toe joint polymer constrained prosthesis is a device made of silicone elastomer or polyester reinforced silicone elastomer intended to be implanted to replace the first metatarsophalangeal (big toe) joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II.

§ 888.3730 Toe joint phalangeal (hemi-toe) polymer prosthesis.

(a) *Identification.* A toe joint phalangeal (hemi-toe) polymer prosthesis is a device made of silicone elastomer intended to be implanted to replace the base of the proximal phalanx of the toe.

(b) *Classification.* Class II.

§ 888.3750 Wrist joint carpal lunate polymer prosthesis.

(a) *Identification.* A wrist joint carpal lunate prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal lunate bone of the wrist.

(b) *Classification.* Class II.

§ 888.3760 Wrist joint carpal scaphoid polymer prosthesis.

(a) *Identification.* A wrist joint carpal scaphoid polymer prosthesis is a one-piece device made of silicone elastomer intended to be implanted to replace the carpal scaphoid bone of the wrist.

(b) *Classification.* Class II.

§ 888.3770 Wrist joint carpal trapezium polymer prosthesis.

(a) *Identification.* A wrist joint carpal trapezium polymer prosthesis is a one-piece device made of silicone elastomer or silicone elastomer/polyester material intended to be implanted to replace the carpal trapezium bone of the wrist.

(b) *Classification.* Class II.

§ 888.3780 Wrist joint polymer constrained prosthesis.

(a) *Identification.* A wrist joint polymer constrained prosthesis is a device made of polyester-reinforced silicone elastomer intended to be implanted to replace a wrist joint. This generic type of device consists of a single flexible across-the-joint component that prevents dislocation in more than one anatomic plane.

(b) *Classification.* Class II.

§ 888.3790 Wrist joint metal constrained cemented prosthesis.

(a) *Identification.* A wrist joint metal constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device prevents dislocation in more than one anatomic plane and consists of either a single flexible across-the-joint component or two components linked together. This generic type of device is limited to a device which is made of alloys, such as cobalt-chromium-molybdenum, and is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a wrist joint metal constrained cemented prosthesis that was in commercial distribution before May 28, 1976. Any other wrist joint metal constrained cemented prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[52 FR 33702, Sept. 4, 1987, as amended at 61 FR 50711, Sept. 27, 1996]

§ 888.3800 Wrist joint metal/polymer semi-constrained cemented prosthesis.

(a) *Identification.* A wrist joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a wrist joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have either a one-part radial component made of alloys, such as cobalt-chromium-molybdenum, with an ultra-high molecular weight polyethylene bearing surface, or a two-part radial component made of alloys and an ultra-high molecular weight polyethylene ball that is mounted on the radial component with a trunnion bearing. The metallic portion of the two-part radial component is inserted into the radius. These devices have a metacarpal component(s) made of alloys, such as cobalt-chromium-molybdenum. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) *Classification.* Class II.

§ 888.3810 Wrist joint ulnar (hemi-wrist) polymer prosthesis.

(a) *Identification.* A wrist joint ulnar (hemi-wrist) polymer prosthesis is a mushroom-shaped device made of a medical grade silicone elastomer or ultra-high molecular weight polyethylene intended to be implanted into the intramedullary canal of the bone and held in place by a suture. Its purpose is to cover the resected end of the distal ulna to control bone overgrowth and to provide an articular surface for the radius and carpus.

(b) *Classification.* Class II.

Subpart E—Surgical Devices

§ 888.4150 Calipers for clinical use.

(a) *Identification.* A caliper for clinical use is a compass-like device intended for use in measuring the thickness or diameter of a part of the body or the distance between two body surfaces, such as for measuring an excised skeletal specimen to determine the proper replacement size of a prosthesis.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§ 888.4200 Cement dispenser.

(a) *Identification.* A cement dispenser is a nonpowered syringe-like device intended for use in placing bone cement (§ 888.3027) into surgical sites.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52953, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

§ 888.4210 Cement mixer for clinical use.

(a) *Identification.* A cement mixer for clinical use is a device consisting of a container intended for use in mixing bone cement (§ 888.3027).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52953, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

§ 888.4220 Cement monomer vapor evacuator.

(a) *Identification.* A cement monomer vapor evacuator is a device intended for use during surgery to contain or remove undesirable fumes, such as monomer vapor from bone cement (§ 888.3027).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 66 FR 38815, July 25, 2001]

§ 888.4230 Cement ventilation tube.

(a) *Identification.* A cement ventilation tube is a tube-like device usually made of plastic intended to be inserted into a surgical cavity to allow the release of air or fluid from the cavity as it is being filled with bone cement (§ 888.3027).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

§ 888.4300 Depth gauge for clinical use.

(a) *Identification.* A depth gauge for clinical use is a measuring device intended for various medical purposes, such as to determine the proper length of screws for fastening the ends of a fractured bone.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§ 888.4505 Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation.

(a) *Identification.* Orthopedic surgical instruments designed for osteochondral implants with press-fit fixation are hand-held devices intended to manipulate bone and cartilage tissue or the implant for the positioning, alignment, defect creation, and placement of press-fit osteochondral implants that utilize no additional means of fixation (*e.g.*, suture fixation, adhesives). This type of device includes instruments specific to the geometry of the implant.

(b) *Classification.* Class II (special controls). The device is exempt from

the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9. The special controls for this device are:

(1) Technical specifications regarding geometry of the instruments must be specified and validated to demonstrate that the instruments can safely position and place the implant.

(2) The patient contacting components of the device must be demonstrated to be biocompatible.

(3) Labeling must include:

(i) Identification of implant(s) and instruments which have been validated for use together; and

(ii) Validated methods and instructions for reprocessing any reusable parts.

[84 FR 57321, Oct. 25, 2019, as amended at 85 FR 44188, July 22, 2020]

§ 888.4540 Orthopedic manual surgical instrument.

(a) *Identification.* An orthopedic manual surgical instrument is a nonpowered hand-held device intended for medical purposes to manipulate tissue, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skid, staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

§ 888.4580 Sonic surgical instrument and accessories/attachments.

(a) *Identification.* A sonic surgical instrument is a hand-held device with various accessories or attachments, such as a cutting tip that vibrates at high frequencies, and is intended for medical purposes to cut bone or other materials, such as acrylic.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 84 FR 71818, Dec. 30, 2019]

§ 888.4600 Protractor for clinical use.

(a) *Identification.* A protractor for clinical use is a device intended for use in measuring the angles of bones, such as on x-rays or in surgery.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§ 888.4800 Template for clinical use.

(a) *Identification.* A template for clinical use is a device that consists of a pattern or guide intended for medical purposes, such as selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§ 888.5850 Nonpowered orthopedic traction apparatus and accessories.

(a) *Identification.* A nonpowered orthopedic traction apparatus is a device that consists of a rigid frame with nonpowered traction accessories, such as cords, pulleys, or weights, and that is intended to apply a therapeutic pulling force to the skeletal system.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of § 820.180, regarding general

requirements concerning records, and §820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 66 FR 38815, July 25, 2001]

§888.5890 Noninvasive traction component.

(a) *Identification.* A noninvasive traction component is a device, such as a head halter, pelvic belt, or a traction splint, that does not penetrate the skin and is intended to assist in connecting a patient to a traction apparatus so that a therapeutic pulling force may be applied to the patient's body.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §888.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 66 FR 38815, July 25, 2001]

§888.5940 Cast component.

(a) *Identification.* A cast component is a device intended for medical purposes to protect or support a cast. This generic type of device includes the cast heel, toe cap, cast support, and walking iron.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §888.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994; 66 FR 38815, July 25, 2001]

§888.5960 Cast removal instrument.

(a) *Identification.* A cast removal instrument is an AC-powered, hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §888.9.

[55 FR 48443, Nov. 20, 1990, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§888.5980 Manual cast application and removal instrument.

(a) *Identification.* A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §888.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records, and §820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 66 FR 38816, July 25, 2001]

PART 890—PHYSICAL MEDICINE DEVICES

Subpart A—General Provisions

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