approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

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

■ 2. Add § 888.3600 to subpart D to read as follows:

§ 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.

Dated: December 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28604 Filed 1–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2022–N–3191]

Medical Devices; Orthopedic Devices; Classification of the Bone Indentation Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the bone indentation device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the bone indentation device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective January 5, 2023. The classification was applicable on August 19, 2021.

FOR FURTHER INFORMATION CONTACT: Laura Rose, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4435, Silver Spring, MD 20993–0002, 301–348–1947, *Laura.rose@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the bone indentation device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in

commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 31, 2021, FDA received Active Life Scientific's request for De Novo classification of the OsteoProbe. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 19, 2021, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 888.1600.[1] We have named the generic type of device bone indentation device, and it is identified as a device that measures resistance to indentation in bone.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—BONE INDENTATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Bone fracture or soft tissue damage	In vivo performance testing, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.
Infection, including operator exposure to infectious transmission.	Shelf-life testing, Sterilization validation, Reprocessing validation, Human factors testing, and Labeling.
Patient or operator injury due to electrical hazards	Electrical safety testing, and Electromagnetic compatibility testing.
Pain, discomfort, bruising, or bleeding	In vivo performance testing, and Labeling.
Inappropriate patient management due to inaccurate device output or misinterpretation of device output.	Non-clinical performance testing, In vivo performance testing, Software verification, validation, and hazard analysis, Human factors testing, and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

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

■ 2. Add § 888.1600 to subpart B to read as follows:

§ 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.

Dated: December 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28601 Filed 1–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9969]

RIN 1545–BP01

Treatment of Special Enforcement Matters; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations; correction.

SUMMARY: This document contains corrections to final regulations (TD 9969) that was published in the **Federal Register** on December 9, 2022. This correction contains final regulations that except certain partnership-related items from the centralized partnership audit regime created by the Bipartisan Budget Act of 2015, and sets forth alternative rules that will apply to the examination of excepted items by the IRS.

DATES: These corrections are effective on January 5, 2023, and are applicable on December 9, 2022.

FOR FURTHER INFORMATION CONTACT: Concerning the final regulations, Jennifer M. Black, at (202)317–6834 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9969) subject to this correction are under section 6241(11) and 6241(7) of the Internal Revenue Code.

Correction of Publication

Accordingly, the final regulations (TD 9969) that are the subject of FR Doc. 2022–26783, published on December 9, 2022, at 87 FR 75473, are corrected to read as follows:

1. On page 75474, in the second column, the fifteenth line from the top of the first full paragraph, the language ''of partner'' is removed.

2. On page 75474, in the second column, the nineteenth line from the top of the first full paragraph is corrected to read ''additional example of an ineligible partner''.

3. On page 75476, in the first column, the last sentence of the first partial paragraph, the language ''adjustment-year'' is corrected to read ''adjustment year'' wherever it appears.

4. On page 75482, in the third column, the twelfth line from the bottom of the first full paragraph, the language ''partner level'' is corrected to read ''partner-level''.

5. On page 75486, in the first column, in the seventh line from the bottom of the second full paragraph, the language ''easily'' is removed.

6. On page 75486, in the second column, in the third line from the bottom of the second full paragraph, the language ''not'' is removed.

Oluwafunmilayo A. Taylor,

Branch Chief, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2022–28594 Filed 1–4–23; 8:45 am]

BILLING CODE 4830–01–P