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 801and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

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 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

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

■ 2. Add § 882.5855 to subpart F to read as follows:

§ 882.5855 Brain stimulation programming planning software.

(a) *Identification.* The brain stimulation programming planning software is a prescription device intended to assist in planning stimulation programming for implanted brain stimulators.

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

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

(2) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(3) Labeling must include:

(i) The implanted brain stimulators for which the device is compatible.

(ii) Instructions for use.

(iii) Instructions and explanations of all user-interface components.

(iv) A warning regarding use of the data with respect to not replacing clinical judgment.

Dated: December 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28603 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–3239]

Medical Devices; Orthopedic Devices; Classification of the Implantable Post-Surgical Kinematic Measurement Knee 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 implantable post-surgical kinematic measurement knee 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 implantable post-surgical kinematic measurement knee 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 27, 2021.

FOR FURTHER INFORMATION CONTACT: Patrick Macatangga, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1567, Silver Spring, MD 20993–0002, 301–796–4369, *Patrick.Macatangga@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the implantable post-surgical kinematic measurement knee 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 October 19, 2020, FDA received Canary Medical, Inc.'s request for De Novo classification of the Canary Tibial Extension with Canary Health Implanted Reporting Processor (CHIRP) System. 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 27, 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 888.3600.[1] We have named the generic type of device implantable post-surgical kinematic measurement knee device, and it is identified as 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.

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—IMPLANTABLE POST-SURGICAL KINEMATIC MEASUREMENT KNEE DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Tissue injury, thermal injury, or electric shock due to device failure including: • Loss of hermeticity. • Battery failure.	Thermal safety testing, Electrical safety testing, Battery safety testing, and Non-clinical performance testing.
Loosening/migration due to device failure at the bone/implant interface	Non-clinical performance testing, and Labeling.
Inaccurate, unreliable, and irreproducible kinematic data leading to improper post-surgical patient management.	Non-clinical performance testing.
Interference with imaging modalities	Non-clinical performance testing, and Magnetic resonance compatibility testing.
Data access failure and delayed access to kinematic data due to: • Software failure. • Interference with other devices. • Use error.	Software verification, validation, and hazard analysis, Electromagnetic compatibility testing, Human factors testing, and Labeling.
Infection	Sterilization validation, Reprocessing validation, Biocompatibility evaluation, and Labeling.
Adverse tissue reaction	Biocompatibility evaluation.

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. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

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

[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.

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