PART 874—EAR, NOSE, AND THROAT DEVICES

■ 1. The authority citation for part 874 continues to read as follows:

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

■ 2. Add § 874.4450 to subpart E to read as follows:

§ 874.4450 Powered insertion system for a cochlear implant electrode array.

(a) *Identification.* A powered insertion system for a cochlear implant electrode array is a prescription device used to assist in placing an electrode array into the cochlea.

(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, including evaluation of all adverse events.

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

(i) Verification of cochlear implant attachment force, release force, and insertion speed;

(ii) Testing to demonstrate the device does not damage or degrade the cochlear implant (including the lead and array portions of the cochlear implant); and

(iii) Comparison testing with manual insertion to evaluate:

(A) Differences in cochlear implant array insertion force associated with use of the device; and

(B) Intracochlear placement of the cochlear implant array (intended scala placement and array insertion depth, together with minimal array tip foldover and cochlear scala translocation).

(3) Usability testing in a simulated hospital environment with an anatomically relevant model (*e.g.,* cadaver testing) that evaluates the following:

(i) Successful use to aid in placement of the electrode array into the cochlea; and

(ii) Harms caused by use errors observed.

(4) Changes in cochlear implant compatibility are determined to significantly affect the safety or effectiveness of the device and must be validated through performance testing or a rationale for omission of any testing.

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

(6) Performance testing must demonstrate the electromagnetic compatibility, electrical safety, and thermal safety of the device.

(7) The patient-contacting components of the device must be demonstrated to be sterile and non-pyrogenic.

(8) Performance testing must support the shelf life of device components provided sterile by demonstrating continued sterility, package integrity, and device functionality over the labeled shelf life.

(9) Software verification, validation, and hazard analysis must be performed for any software components of the device.

(10) Labeling must include:

(i) The recommended training for the safe use of the device;

(ii) Summary of the relevant clinical and non-clinical testing pertinent to use of the device with compatible electrode arrays; and

(iii) A shelf life.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00008 Filed 1–5–23; 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–3190]

Medical Devices; Orthopedic Devices; Classification of the Resorbable Shoulder Spacer

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the resorbable shoulder spacer 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 resorbable shoulder spacer'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 6, 2023. The classification was applicable on July 12, 2021.

FOR FURTHER INFORMATION CONTACT: Farzana Sharmin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4564, Silver Spring, MD 20993–0002, 301–796–4067, *Farzana.Sharmin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the resorbable shoulder spacer 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 June 12, 2020, FDA received Ortho-Space, Ltd.'s request for De Novo classification of the InSpace Subacromial Tissue Spacer 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 July 12, 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 888.3630.[1] We have named the generic type of device resorbable shoulder spacer, and it is identified as a device 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.

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—RESORBABLE SHOULDER SPACER RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
No improvement in shoulder function and pain reduction due to device failure from: • Device migration • Device malposition • Device collapse	Clinical performance testing; Non-clinical performance testing; Animal performance testing; and Labeling.
Increased risk of adverse events of the index shoulder (*e.g.,* pain, spasm, and swelling, subsequent medical and surgical treatments secondary to disease progression).	Clinical performance testing; and Labeling.
Adverse tissue reaction	Biocompatibility evaluation; Animal performance testing; Non-clinical performance testing; and Labeling.
Infection	Sterilization validation; Pyrogenicity testing; Shelf life 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.

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

[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.

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 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 part 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, 360*l,* 371.

■ 2. Add § 888.3630 to subpart D to read as follows:

§ 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.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00012 Filed 1–5–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2022–N–3131]

Medical Devices; Physical Medicine Devices; Classification of the Electroencephalography-Driven Upper Extremity Powered Exerciser

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the electroencephalography (EEG)-driven upper extremity powered exerciser 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 electroencephalography (EEG)-driven upper extremity powered exerciser'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 6, 2023. The classification was applicable on April 23, 2021.

FOR FURTHER INFORMATION CONTACT: Heather Dean, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4214, Silver Spring, MD, 20993–0002, 240–402–9874, *Heather.Dean@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the electroencephalography (EEG)-driven upper extremity powered exerciser 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