

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 management 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 874

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 874 is amended as follows:

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, 360l, 371.

■ 2. Add § 874.6000 to subpart F to read as follows:

§ 874.6000 Transcutaneous electrical nerve stimulator for the relief of congestion.

(a) *Identification.* A transcutaneous electrical nerve stimulator for the relief of congestion is a device that electrically stimulates the skin overlying the paranasal sinuses to relieve congestion.

(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, including electrical stimulation parameters that must be specified and verified.

(2) Performance data must demonstrate the electromagnetic compatibility, battery safety, and electrical safety of the device.

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

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

(5) Human factors testing must demonstrate that users can successfully use the device in the intended use environment based solely on its labeling and instructions for use.

(6) Labeling must include the following:

(i) Instructions for use, including images that demonstrate how to use the device;

(ii) Device specifications, including the number of channels, output waveform, stimulation peak voltage and current, pulse duration, frequency, maximum current density, maximum phase charge, and power source; and

(iii) Explanations of the user-interface components.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2026–N–2887]

Medical Devices; Orthopedic Devices; Classification of the Manual Surgical Instrument for Appropriate Patient Selection for Orthopedic Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the manual surgical instrument for appropriate patient selection for orthopedic implant 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 classification of the manual surgical instrument for appropriate patient selection for orthopedic implant. We are taking this action because we have determined that classifying the device into class II 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 in part by reducing regulatory burdens.

DATES: This order is effective April 16, 2026. The classification was applicable on May 28, 2019.

FOR FURTHER INFORMATION CONTACT:

David Hwang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4568, Silver Spring, MD 20993–0002, 301–796–3217, David.Hwang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the manual surgical instrument for appropriate patient selection for orthopedic implant as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness for its intended use. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into the appropriate device class based on risk and the regulatory controls sufficient to provide reasonable assurance of safety and effectiveness.

FDA may classify a device through an accessory classification request under section 513(f)(6) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)), established by section 707 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52). The provision allows manufacturers or importers to request classification of an accessory distinct from another device upon written request. The classification is based on the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request appropriate classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days of announcing the classification.

Alternatively, under section 513(f)(6)(C) of the FD&C Act, a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to

the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days of announcing the classification.

II. Accessory Classification

On March 4, 2019, FDA received Intrinsic Therapeutics Inc.’s request for accessory classification of the Defect Measurement Tool for the Barricaid Anular Closure Device. 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 section 513(a)(1)(B) of the FD&C Act). 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 May 28, 2019, 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 888.4510.¹ We have named the generic type of device “manual surgical instrument for appropriate patient selection for orthopedic implant,” and it is identified as an orthopedic manual surgical instrument used to measure an anatomical feature(s) to determine appropriate patient selection for an orthopedic implant. The characteristics of the instrument are defined by the specifications set for the orthopedic implant in terms of geometry, surgical technique and use of the device.

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—MANUAL SURGICAL INSTRUMENT FOR APPROPRIATE PATIENT SELECTION FOR ORTHOPEDIC IMPLANT RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Reprocessing validation, and Labeling.
Improper assessment of size of defect	Nonclinical performance testing.
Inadvertently enlarging the size of the defect	Nonclinical performance testing.

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.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. At a future date, we may publish a separate notice in the **Federal Register** announcing our intent to exempt this device type. 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 part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in the guidance document “Medical Device Accessories—Describing Accessories and Classification Pathways” have been approved under OMB control number 0910–0823; 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 21 CFR part 820 regarding quality management system regulation have been approved

under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; 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, 360l, 371.

- 2. Add § 888.4510 to subpart E to read as follows:

§ 888.4510 Manual surgical instrument for appropriate patient selection for orthopedic implant.

(a) *Identification.* This device is an orthopedic manual surgical instrument used to measure an anatomical

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.

feature(s) to determine appropriate patient selection for an orthopedic implant. The characteristics of the instrument are defined by the specifications set for the orthopedic implant in terms of geometry, surgical technique and use of the device.

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

(1) Technical specifications regarding geometry of the instruments must be identified and validated to demonstrate that the instruments accurately measure the critical geometry for patient selection of the intended orthopedic implant.

(2) The use of the instruments is validated to demonstrate that the measurement process does not alter the patient anatomy which is being measured.

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

(4) Labeling must include:

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

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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2020-N-1053]

Physical Medicine Devices; Reclassification of Non-Invasive Bone Growth Stimulators

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify non-invasive bone growth stimulators (product codes LOF and LPQ), postamendments class III devices, into class II, subject to premarket notification. FDA is codifying the reclassification of these devices under the new classification regulation, “non-invasive bone growth stimulator.” FDA is also establishing the special controls necessary to provide reasonable assurance of safety and effectiveness of these devices.

DATES: This order is effective May 18, 2026.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: John Gomes, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4564, Silver Spring, MD 20993, 301-796-5618, John.Gomes@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not introduced or delivered for introduction into interstate commerce for commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until (1) the Food and Drug Administration (FDA, the Agency, or we) reclassifies the device into class I or II; or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices using the procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and our implementing regulations (21 CFR part 807, subpart E).

A postamendments device that has been initially classified into class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act, which provides that FDA, acting by administrative order, can reclassify the device into class I or II on its own initiative, or in response to a petition

from the manufacturer or importer of the device. To change the classification of the device, the new class must have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

FDA relies upon “valid scientific evidence,” as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2), in the classification process to determine the level of regulation for devices. In general, to be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available and excludes trade secret and/or confidential commercial information, such as the contents of a pending premarket approval application (PMA) (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act (the “six-year rule”) provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of the device, but it does not include descriptions of methods of manufacture and product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the requirements under section 510(k) of the FD&C Act if FDA determines that a premarket notification (510(k)) is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

On August 17, 2020, FDA published in the **Federal Register** a proposed order¹ to reclassify non-invasive bone growth stimulators intended to promote osteogenesis as an adjunct to primary treatments for fracture fixation and spinal fusion or as a treatment for established nonunions or failed fusions² (product codes LOF and LPQ)^{3,4} from class III into class II,

¹ FDA notes that the “ACTION” caption for the proposed order was styled as “Proposed amendment; proposed order; request for comments,” rather than “Proposed 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.

² The intended use language adopted in this final order adds “or as a treatment for established nonunions or failed fusions” to the original intended use language presented in section III of the proposed order (85 FR 49986 at 49989).

³ FDA’s Center for Devices and Radiological Health (CDRH) uses product codes to help categorize and ensure consistent regulation of