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.

[FR Doc. 2026–07367 Filed 4–15–26; 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–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 order [1] 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 fusions [2] (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

subject to premarket notification (85 FR 49986 (August 17, 2020), the ''proposed order''). FDA has considered the information available to the Agency, including certain information in PMAs in accordance with the six-year rule,[5] peer-reviewed literature, the deliberations of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee convened on September 8–9, 2020 (the ''Panel'') to discuss non-invasive bone growth stimulators and the proposed reclassification (as discussed in section II of this final order), as well as comments from the public docket on the proposed order (as discussed in section III of this final order), to determine whether there is sufficient information to establish special controls to effectively mitigate the risks to health (updated, as discussed in section IV of this final order). FDA has also determined based on this information that the special controls, together with general controls, provide a reasonable assurance of safety and effectiveness when applied to these devices.

Therefore, in accordance with section 513(f)(3) of the FD&C Act, FDA, on its own initiative, is issuing this final order [6] 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 fusions from class III to class II (special controls). Absent the special controls identified in this final order, general controls applicable to the device type are insufficient to effectively mitigate the risks identified for this device type, and therefore insufficient to provide reasonable assurance of the safety and effectiveness of these devices.

For these class II devices, instead of a PMA, manufacturers may submit a premarket notification and obtain FDA clearance of the devices before marketing them. This action will decrease regulatory burden on industry, as manufacturers will no longer have to submit a PMA for these types of devices but can instead submit a 510(k) to the Agency for clearance prior to marketing their device. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately provides patients with more timely access to these types of devices. FDA expects that the reclassification of these devices would enable more manufacturers to develop these types of devices such that patients will benefit from increased access to non-invasive bone growth stimulators for which there is a reasonable assurance of safety and effectiveness.

II. Deliberations of the Panel Meeting

A. Summary of Panel Discussion

On September 8, 2020, the Panel met to discuss and make recommendations regarding the proposed reclassification of non-invasive bone growth stimulators from class III into class II (Ref. 1). At the Panel meeting, FDA presented the regulatory history,[7] risks to health, mitigations, and special controls described in the proposed order (85 FR 49986).

The Panel generally agreed with the risks to health identified by FDA and provided recommendations to better qualify and define some of the risks to health, as discussed in section II.B of this final order.

The Panel unanimously agreed that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for non-invasive bone growth stimulators. The Panel also unanimously agreed that non-invasive bone growth stimulators are not life-supporting or life-sustaining. The Panel generally agreed with FDA that these devices are not of substantial importance in preventing impairment of human health, though one Panel member disagreed on the grounds that if the device failed to work as intended to treat an established nonunion, that failure may have significant health impacts rising to the level of substantial importance in preventing impairment of human health. The Panel unanimously agreed that non-invasive bone growth stimulators do not present a potential unreasonable risk of illness or injury.

The Panel unanimously agreed that sufficient information exists to develop special controls for these devices. The Panel deliberated on whether the special controls proposed by FDA appropriately mitigate the identified risks to health for this device type, and whether additional or different special controls should be considered. The Panel generally agreed with FDA's proposed special controls and recommended additional special controls. The Panel recommended that the special controls include specific requirements to ensure a rigorous clinical data set and postmarket surveillance as a means of assessing longer-term performance. The Panel also recommended that the special controls include measures beyond labeling to address risks related to interference with other electronic devices.

In conclusion, while the Panel recommended revisions to the risks to health and additional special controls (as discussed in section II.B of this final order), it generally agreed that non-invasive bone growth stimulators met each of the criteria that would support FDA's proposed reclassification of these devices from class III into class II, subject to premarket notification and special controls to mitigate the identified risks to health for these devices.

B. FDA Responses to Panel Deliberations and Changes in the Final Order

FDA considered the Panel's comments and recommendations and, as described below, either modified the final order in response to Panel feedback or explained why we disagreed with the Panel.

1. Risks to Health

The Panel recommended that FDA clarify the risk of adverse interactions with other devices and include additional mitigation measures for these risks beyond labeling. Accordingly, FDA

medical devices. A product code consists of three characters that are assigned at the time a product code is generated and is unique to a product type. The three characters carry no other significance and are not an abbreviation.

[4] Invasive bone growth stimulators, designated under product code LOE, are outside the scope of this reclassification final order.

[5] In support of this reclassification, FDA, on its own initiative, relied on certain data from relevant original PMAs and relevant PMA panel-track supplements, available to FDA with product code of LOF, in accordance with the six-year rule (see section 520(h)(4) of the FD&C Act (21 U.S.C. 360j(h)(4))) (See also, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-section-216-food-and-drug-administration-modernization-act-1997-guidance-industry-and-fda*). This includes data from relevant original PMAs and relevant PMA panel-track supplements approved after November 28, 1990, and before Jan 1, 2020, as noted in section VII of the proposed order (85 FR 49986 at 49990). FDA's PMA database can be found at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm*. For the purpose of this final order, PMA data considered in accordance with section 520(h)(4) include only that data which was submitted to and therefore considered by FDA at the time the PMA was reviewed and approval was issued.

[6] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' (See footnote 1 for explanation of editorial change.)

[7] The regulatory history of these devices includes significant action around a 2005 petition for reclassification that was referred to the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. In 2006, that panel met to consider the petition and its recommendations were published in the **Federal Register** on January 17, 2007 (72 FR 1951). The petitioner subsequently withdrew their petition and the action was closed. In 2015, FDA identified non-invasive bone growth stimulators as a potential candidate for reclassification (80 FR 23798) and subsequently proposed to reclassify these devices by administrative order on its own initiative, taking into account the regulatory history of the device type (85 FR 49986).

reevaluated the risks to health and mitigation measures for adverse interaction with internal/external fixation devices and electromagnetic interference (EMI). FDA made minor revisions in section IV of this final order to clarify in the identified risks that tissue damage is a result of heating of the fixation device which, in turn, leads to heating (damage) of the tissue. FDA also reconsidered mitigations for this risk to health and concluded that thermal safety is an important consideration, as signal outputs could induce currents in metal implants (for modalities that employ electromagnetic fields) or could cause deep tissue heating (for ultrasound-based devices). We therefore revised the mitigation measures for this risk in section IV of this final order to include non-clinical performance testing, which would include an evaluation of thermal safety and thermal reliability. FDA also revised relevant parts of the non-clinical performance testing special control at 21 CFR 890.5870(b)(2) to clarify that thermal safety and thermal reliability must be verified and validated. This could be demonstrated through non-clinical performance testing, for example, using applicable consensus standards (*e.g.,* IEC 60601 series of standards for the basic safety and essential performance of medical electrical equipment), or other validated methods.

In addition, we revised the EMI risk in section IV of this final order to clarify that patient harms could result from interference between non-invasive bone growth stimulators and electrically powered implanted devices (*i.e.,* non-invasive bone growth stimulators may interfere with implanted devices and vice versa), and also due to interference from electronically powered devices in the environment (such as radio-frequency emitting household electrical equipment). While implanted electrical devices (*e.g.,* pacemakers or nerve stimulators) may have been designed to have immunity to certain electromagnetic fields, there is potential for the electromagnetic fields of non-invasive bone growth stimulators to interfere with implanted devices, or for the electromagnetic fields of implanted devices to cause electromagnetic interference with non-invasive bone growth stimulators. Furthermore, internal/external fixation devices in the proximity of non-invasive bone growth stimulators may similarly interfere with the treatment signal or lead to heating of the fixation device, which could lead to heating and damage of the surrounding tissue. We believe the mitigation measures (electromagnetic compatibility (EMC) testing and labeling) address these risks, and that no further revisions to the mitigation measures for the EMI risk are necessary. As a potential method of EMC testing to mitigate EMI risks, FDA suggests using FDA-recognized consensus standards [8] for medical electrical equipment safety and electromagnetic compatibility, including *IEC 60601–1–2 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests* (Ref. 2). Additional collateral standards within the IEC 60601 series of standards may also apply, depending on the technology used in the device. Additionally, the labeling special control requires appropriate warnings for patients with implantable devices. Consistent with aforementioned consensus standards, such warnings in the labeling should specify appropriate separation distances, when applicable.

The Panel recommended that the risk of adverse biological effects either be better defined or otherwise removed from the list of risks to health associated with non-invasive bone growth stimulators. FDA maintains that this risk should be included, given that signals with select characteristics could induce adverse biologic effects outside of thermal risks. We have revised the description of this risk to health in section IV of this final order to address the Panel's recommendation and list the signal characteristics that may lead to adverse biologic effects.

During the Panel's discussion of the risks to health, the Panel Chair summarized an additional concern as ''if the signal characteristics themselves need to be defined in a way that characterized safety and efficacy in a way that was independent from the field characteristics'' (Ref. 3 at lines 3135–37). FDA does not believe any changes beyond those already detailed in this section are necessary to address this concern. The Panel did not identify a specific risk to health, and the stated concerns are already captured in the risks identified in section IV of this final order such as failure or delay of osteogenesis, adverse interaction with internal/external fixation devices, adverse biologic effects, and burn.

[8] FDA recognizes certain voluntary consensus standards for medical devices, which are identified in a database available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.*

2. Criteria for Classification

Most of the Panel agreed that non-invasive bone growth stimulators met the criteria for classification into class II. The Panel unanimously agreed that general controls alone are not sufficient to provide reasonable assurance of safety and effectiveness, that non-invasive bone growth stimulators do not present a potential unreasonable risk of illness or injury, and that sufficient information exists to establish special controls for non-invasive bone growth stimulators. All but one Panel member agreed that non-invasive bone growth stimulators are not ''life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health.'' This Panel member disagreed on the grounds that if the device failed to work as intended to treat an established nonunion, that failure may have significant health impacts rising to the level of substantial importance in preventing impairment of human health. Other Panel members responded with the view that the impairment was the nonunion and a failure to heal the nonunion was not itself the cause of the nonunion. We additionally note that FDA identified (and the Panel concurred) that failed or delayed osteogenesis is a risk for this device, but measures such as clinical and non-clinical performance testing would mitigate the risk of failed or delayed osteogenesis and provide a reasonable expectation of the effectiveness of various treatment uses. FDA agrees with the majority of the Panel that this device type meets all of the criteria for regulation as a class II device.

3. Special Controls

The Panel recommended adding a special control for postmarket surveillance to monitor device effectiveness in real-world clinical practice. FDA disagrees. Postmarket surveillance as described by the Panel is not necessary to demonstrate reasonable assurance of safety and effectiveness. The safety profile of non-invasive bone growth stimulators is based on a long history of use of these devices and supports FDA's position that these devices do not pose sufficient safety concerns to warrant postmarket surveillance beyond standard postmarket requirements (*i.e.,* medical device reporting (MDR) requirements). Consistent with this safety profile, none of the non-invasive bone growth stimulator devices currently on the market under an approved PMA has required or relied on post-approval studies. Additionally, FDA's clinical

data special control will help ensure there is sufficient evidence that the device performs as intended without the need to rely upon postmarket data for this determination.

The Panel additionally recommended that the clinical data special control include specific requirements to ensure a rigorous data set, such as specifying imaging modalities and a follow-up study of at least one year to confirm that the device is effective for its intended use. As discussed in more detail in our response to comment 2 in section III of this final order, the clinical data special control sets the expectation that manufacturers will provide robust clinical data to demonstrate that the device performs as intended under the anticipated conditions of use. FDA disagrees that it is necessary to specify prescriptive imaging modalities or the length of follow-up for a premarket clinical study. Appropriate timeframes for follow-up studies depend on the type of fracture and anatomic site being treated, as the timeframes to achieve fusion may vary. As such, the special control for clinical performance data has been purposefully written in a way to allow for flexibility in the endpoints and measures used to demonstrate patient benefits and mitigation of risks for this device type. However, to help ensure that clinical data meets appropriate fusion endpoints for the device's intended use, we added a requirement in the clinical data special control at 21 CFR 890.5870(b)(1) that ''[i]maging data must demonstrate fusion at the treatment site.''

III. Comments on the Proposed Order

A. Introduction

FDA received comments from fewer than 10 commenters on the proposed order (85 FR 49986) published in the **Federal Register** on August 17, 2020. The comment period on the proposed order closed on October 16, 2020. Comments received by the close of the comment period were from Congressional representatives, a trade organization, an orthopaedic scientist-surgeon, and other interested parties. Some of the comments contained one or more comments on one or more issues. Some comments supported the proposed reclassification, and others recommended against reclassification. Various comments included recommendations for special controls that commenters believed were necessary to establish reasonable assurance of safety and effectiveness.

We describe and respond to the comments in section III.B of this final order. The order of the comments and responses is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received. To provide organized and efficient responses to similar issues, we grouped comments by similar subject matter, and, in some cases, we treated different subjects presented by the same commenter as distinct comments.

B. Description of Comments and FDA Response

(Comment 1) Various commenters agreed with the proposal to reclassify non-invasive bone growth stimulators into class II. These comments generally spoke to the importance of patient access and the relatively low risk of these devices. They also stated that a lower classification (*i.e.,* class II instead of class III) could expedite bringing new non-invasive bone growth stimulators to market. Two comments, representing multiple interested parties, disagreed with FDA, asserting that non-invasive bone growth stimulators should be retained in class III because class II controls are insufficient to provide reasonable assurance of safety and effectiveness.

(Response 1) FDA agrees with the comments supporting reclassification of non-invasive bone growth stimulators into class II and disagrees that these devices should be retained in class III. Based on publicly available scientific evidence presented in the proposed order and to the Panel, and taking into consideration feedback from the Panel and comments received on the proposed order, FDA has determined that reclassification of non-invasive bone growth stimulators into class II, subject to premarket notification, is appropriate because general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish special controls to provide such assurance. The Panel also unanimously agreed that non-invasive bone growth stimulators met the criteria for classification into class II.

Additionally, class III is inappropriate because FDA has determined, and a large majority of the Panel agreed, that non-invasive bone growth stimulators are not for use in supporting or sustaining human life, are not of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury.

We also agree with commenters that this reclassification may have a positive impact on bringing new non-invasive bone growth stimulators to market more quickly. As discussed in section I of this final order, reclassifying non-invasive bone growth stimulators into class II will reduce regulatory burdens on industry because instead of submitting a PMA, manufacturers may submit a less burdensome 510(k) to obtain FDA clearance of the device before marketing it, among other lesser regulatory requirements. We expect that this would, in turn, increase access to safe and effective therapeutics for which there is still a reasonable assurance of safety and effectiveness. The 510(k) pathway is less burdensome and generally more cost-effective for industry and FDA than the PMA pathway, the most stringent type of device marketing application required by FDA. A 510(k) typically results in a shorter premarket review timeline compared to a PMA, which ultimately provides more timely access of these types of devices to patients.

(Comment 2) A couple commenters provided recommendations regarding the quality of clinical performance data that FDA should require to support future marketing submissions for non-invasive bone growth stimulators. One commenter suggested that special controls should require high-quality clinical data without commenting on whether non-invasive bone growth stimulators should be reclassified. Another commenter stated that non-invasive bone growth stimulators should remain a class III device, but if FDA proceeds with reclassification, certain data quality standards should apply. These commenters emphasized the importance of prospective, randomized clinical trials to ensure these submissions include robust clinical evidence. One commenter additionally recommended that future clinical studies employ similar clinical trial design parameters as those used in pivotal studies for currently approved non-invasive bone growth stimulators, using clinically relevant endpoints based on imaging data and clinical measures of a subject's healing or functioning. The commenter also specified that the clinical data should be derived from clinical trials rather than citation of published literature.

(Response 2) While FDA agrees that high-quality clinical data is necessary to support 510(k)s for non-invasive bone growth stimulators, FDA disagrees that the clinical data special control should specifically require prospective, randomized clinical trials to demonstrate the effectiveness of new devices brought to the market. FDA also agrees that imaging data should be required to demonstrate device effectiveness and we have revised the clinical data special control accordingly,

as further described in section II.B.3 of this final order.

We also note that data supporting approved PMAs for non-invasive bone growth stimulators were based on a range of sources that did not always include prospective randomized clinical trials. While a randomized, controlled clinical study is the highest standard for data quality, there are many sources of robust, quality clinical data that meet FDA standards for ''valid scientific evidence'' (21 CFR 860.7), including non-randomized studies compared to registry data, or other sources of real-world evidence. Therefore, the special controls we are finalizing for non-invasive bone growth stimulators are intentionally flexible and purposefully not intended to limit the types of clinical evidence that may support a 510(k) for these devices.

As discussed in the proposed order, differences in treatment waveform and frequency can have unknown effects on the healing pathway, resulting in significant effects on reported device effectiveness (85 FR 49986 at 49991). Therefore, to demonstrate substantial equivalence, clinical performance data must demonstrate that the device performs as intended in the indicated patient population. FDA recommends that the clinical study be sufficiently robust to adequately support the proposed indications for use for the device. A randomized prospective clinical trial would suffice, however, in certain circumstances, other forms of clinical evidence, such as real-world evidence, would also be adequately robust to support a substantial equivalence determination. Such data should be scientifically valid and include sufficient information to demonstrate a clinically meaningful benefit of the device and describe the expected safety profile, as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2).

Additionally, to demonstrate that the device performs as intended under anticipated conditions of use, the data should represent the intended patient population and intended anatomic location of the device. The study should include appropriate, clinically relevant endpoints. While the endpoint will depend on the device's specific indications for use, independent radiographic assessment of bone fusion using a clinically recognized scale and validated assessments of clinical healing are examples of appropriate endpoints. To support a demonstration of substantial equivalence, the study should also include sufficient evidence that the device performs equivalently to a legally marketed predicate device. If the subject device is not studied in conjunction with the predicate device, we recommend that the study design demonstrate a clinically meaningful and statistically significant improvement compared to an appropriate control (*e.g.,* sham device). A side-by-side study could also be used to demonstrate substantial equivalence in clinically relevant endpoints (*e.g.,* time to radiographic and clinical healing) between the subject device and a legally marketed predicate.

In lieu of using new clinical data to support a 510(k), applicants may be able to rely on clinical data from a legally marketed non-invasive bone growth stimulator with the same intended use and indications for use, if the applicant demonstrates that the critical signal parameters and operational modality of their device are sufficiently similar to those of the legally marketed device. This approach is consistent with leveraging publicly available data to support approval of a PMA.[9] Further, we revised the labeling special control in this final order to require ''a detailed summary of the supporting clinical data'' rather than ''a detailed summary of the clinical testing'' as initially proposed to more accurately represent the sources of data that may be relied upon for a 510(k). As stated above, if the applicant demonstrates that the critical signal parameters of their device are sufficiently similar to those of a legally marketed predicate device, then the ''supporting clinical data'' may include clinical data sets generated using that predicate device.[10]

The special controls for non-invasive bone growth stimulators include controls for clinical data and non-clinical performance testing that could support unique study designs that are appropriate for the specific indications for use and technological characteristics for each device that would be reviewed in a 510(k).[11] While every clinical study developed to support a premarket submission for non-invasive bone growth stimulators should be designed to demonstrate that the device performs as intended when used in the intended patient population, the final special controls for these devices allow for customized study designs tailored specifically for each device considering the device technology and indications for use. Reclassification of these devices from class III into class II does not exclude the need for device-specific clinical data and non-clinical performance testing. Rather, the special controls establish requirements for such data and testing that is necessary to support reasonable assurance of safety and effectiveness.

This flexibility is also important for non-clinical performance testing special control requirements, which include validation and verification of thermal safety and thermal reliability, that signal characteristics are within safe physiologic limits, and that device reliability is consistent with the expected use-life. An applicant may validate and verify these safety and performance characteristics in a variety of ways, as discussed in the following paragraphs. Note that the non-clinical performance testing special control also requires validation and verification of critical performance characteristics, which we discuss in our response to comment 4 in this section of the final order.

Given the potential for devices of this type to cause patient harm due to heating from multiple sources, the non-clinical special control requires validation and verification of thermal safety and thermal reliability. First, as the control units are often worn on a patient's belt and are battery powered, excessive heating of the control unit for prolonged duration may cause thermal damage to the patient's skin and

[9] Examples of approved PMAs for non-invasive bone growth stimulators that have leveraged publicly available clinical data in their submissions since December 2020, in accordance with the 6-year rule (see section 520(h)(4) of the FD&C Act), include P190030, P210035, P230025, P210016 (Refs. 4–7). While the 6-year rule applies only to PMAs, 510(k)s may be able to leverage clinical information and data from a sufficiently similar predicate device, assuming the sponsor has proper access to such data.

[10] Under 21 CFR 807.92(b)(2), when the determination of substantial equivalence is based in part on an assessment of clinical performance data, the summary should include a brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence.

[11] A manufacturer may seek FDA input on non-clinical or clinical study design by utilizing our Q-Submission program, through which FDA may provide input on device-specific requirements and recommendations for non-clinical and clinical studies intended to support device-specific indications for use. Additional information regarding the Q-Submission program can be found in FDA's final guidance document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (Ref. 8). In addition, reclassification does not change the regulatory requirements related to clinical study oversight and investigational device exemptions (IDEs) in 21 CFR part 812 or patient protections in 21 CFR part 50 and 56. FDA may provide specific feedback and study design considerations for clinical studies as a part of an IDE review for significant risk studies.

subdermal tissue. Second, the transducer itself may heat up during use, causing similar injury at the treatment site if it is patient-contacting. Finally, the signal itself may cause heating of deep tissue. This could be due to the electromagnetic fields generated by pulsed electromagnetic field (PEMF) and combined magnetic field (CMF) devices inducing currents in nearby metal implants, current leaks in capacitive coupling (CC) devices causing electrical burns, or low intensity pulsed ultrasound (LIPUS) devices causing deep tissue heating due to the mechanical effects of ultrasound signals. Testing results to appropriate standards (if applicable) to demonstrate that the device does not cause unsafe heating should be included in support of a 510(k). Literature or other scientific evidence can also be used to support the generally accepted thermal safety of the subject device's treatment signal.

Validation and verification that signal characteristics are within safe physiologic limits is required to mitigate the potential for patient harm from the generated signal, which could be due to various factors such as ultrasonic heating or tissue cavitation, excessive electrical current which could damage tissue, or electromagnetic fields which may interfere with biological function. Applicants should provide signal characterization to evaluate the nature of their device and provide scientific evidence and rationale demonstrating that the device generates a physiologically safe signal, which may include non-clinical animal testing,[12] side-by-side bench testing to demonstrate that the device signal falls within the range of a predicate device, or literature to demonstrate that similar signals have a history of safe use.

Validation and verification that device reliability is consistent with the expected use-life of the device is required because these devices are generally used daily by patients for several months and may be exposed to a large amount of physical wear. A 510(k) should provide evidence that the device can perform within specifications throughout its labeled use-life. One form this evidence may take is simulated use testing of the device. Considerations for the reliability testing special control (21 CFR 890.5870 (b)(2)(iv)) should include (as applicable), but not be limited to, continued integrity of all connection ports, repeated battery connection and disconnection, battery performance after repeated charging/discharging, integrity of all buttons/switches, performance of components after repeated reprocessing, activation of transducer for the full use-life of the device, and environmental exposure (*e.g.,* humidity).

(Comment 3) One commenter expressed concern that, by publishing the proposed order in the **Federal Register** in advance of the Panel meeting, ''FDA has already prejudged the outcome'' of the meeting and would potentially influence the Panel's recommendations.

(Response 3) FDA complied with all statutory and regulatory requirements in its proposal to reclassify non-invasive bone growth stimulators under section 513(f)(3) of the FD&C Act, which allows, but does not require, FDA to convene a classification panel and does not prescribe when the panel meeting and proposed order must occur in relation to each other. In the preamble to the final rule updating FDA's medical device classification procedures regulations to reflect updates made to the FD&C Act in 2012 by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 122–144), FDA stated its intent to issue a reclassification proposed order under section 513(f)(3) before holding the classification panel meeting (83 FR 64443 at 64451 (December 17, 2018)). FDA's statement was in response to comments from interested parties suggesting that Congress intended this order when they passed FDASIA (83 FR at 64450). Since then, in cases when FDA has elected to convene a classification panel for a potential reclassification action under section 513(f)(3) of the FD&C Act, FDA has generally issued the proposed order before convening the panel.

(Comment 4) More than one commenter noted the wide range of technologies that have been approved as non-invasive bone growth stimulators and expressed concern that class II special controls could not be established to provide reasonable assurance of safety and effectiveness for the generic device type at least in part because of this wide range of technologies.

(Response 4) While we acknowledge that FDA has approved PMAs for non-invasive bone growth stimulators with an array of different technologies (*e.g.,* PEMF, CMF, CC, and LIPUS), we disagree that special controls cannot be established to provide reasonable assurance of safety and effectiveness. Furthermore, as discussed in section II.A of this final order, the Panel also unanimously agreed with FDA's conclusion that sufficient information exists to establish special controls.

In evaluating whether non-invasive bone growth stimulators should be reclassified into class II, we considered the risks to health and risk mitigations associated with the different technologies of approved devices. As part of this assessment, we evaluated peer-reviewed literature, MDRs, recalls, and additional information (*e.g.,* the Summary of Safety and Effectiveness from PMAs subject to the six-year rule[13]). FDA concluded that the risks to health associated with approved non-invasive bone growth stimulators, and the appropriate mitigations of those risks, are the same across all modalities. For this reason, the special controls provide flexibility while still requiring manufacturers to account for the critical characteristics of their particular technology. While the specific testing necessary to mitigate risks for a particular device may differ by technology, the special controls are written broadly enough to apply to all non-invasive bone growth stimulators, regardless of technology.

For example, the non-clinical performance data special control (21 CFR 890.5870(b)(2)) requires validation and verification of critical performance characteristics to ensure that intended design outputs are delivered to the patient. This particular special control is broadly written to allow for flexibility in terms of which specific design outputs are relevant based upon the modality of the device. To fully describe the specific device and allow for a comparison to the predicate, we suggest providing a full and complete characterization of both the device and the therapeutic signal in the 510(k). We recommend that characterization of the signal waveform include images and a sufficiently detailed description to ensure continued treatment effectiveness. Because of the wide range of signal modalities applicable to non-invasive bone growth stimulators (*e.g.,* PEMF, CMF, CC, and LIPUS), it is not possible to list every treatment signal parameter that should be assessed; however, in general, we recommend including the following (as applicable): output signal shape, magnitude, primary frequency, carrier frequency, duty cycle, focal depth, magnetic flux, effective radiating area, total average power, spatial average-temporal average intensity, beam non-uniformity ratio, and any other measure needed to fully characterize the treatment signal.

[12] FDA supports the principles of the ''3Rs,'' to replace, reduce, and/or refine animal use in testing when feasible. 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.

[13] See footnote 5 for information regarding the PMAs relied on to support this reclassification.

Additionally, different treatment signals will pass through human tissue and bone in different ways. Consequently, while the device may be generating a treatment signal of a specific amplitude or waveform, the treatment site may be receiving a different signal. This could be caused by signal loss from the transducer/air/skin interface, or due to absorption of signal power or certain frequencies as the signal passes through soft and hard tissue. Therefore, we recommend applicants include results from validation testing to assess the signal reaching the treatment site. While it is not possible to consider every treatment attenuation scenario, we recommend applicants demonstrate that the intended treatment parameters are delivered throughout a sufficient volume to encompass the treatment site in the indicated patient population. Examples of testing may include measurement of the signal in an appropriate surrogate (*e.g.,* phantom model).

(Comment 5) One commenter requested that FDA issue a special controls guidance to outline additional detail regarding ''key parameters for clinical studies and other data (labeling comprehension and device usability testing) to support marketing of never before-authorized [non-invasive] bone growth stimulator devices.''

(Response 5) While we do not intend to issue a guidance document to accompany the special controls identified in this final order for non-invasive bone growth stimulators at this time, the preamble to this final order has recommendations and examples for how manufacturers may comply with the special controls. In section II.B of this final order, in response to Panel feedback, we provide examples of recognized consensus standards for EMC testing that would mitigate EMI risks to satisfy the performance data special control for EMC. In our responses to comments 2 and 4 in this section of this final order, we provide examples of the different types of clinical data, clinical studies, and non-clinical performance data that could support a 510(k) for non-invasive bone growth stimulators. FDA reviews the non-clinical and clinical data and related valid scientific evidence included in a 510(k) to assess substantial equivalence to a legally marketed predicate device, including, as appropriate, conformance to special controls.

We have also revised the special controls for non-invasive bone growth stimulators to provide more detail and clarity on FDA's expectations for clinical data and non-clinical performance testing. Additionally, as discussed in section II.B.3 and in our response to comment 2 in this section of the final order, the clinical data special control now requires imaging data to further support device effectiveness. Non-clinical performance testing now more clearly requires verification and validation of critical performance and safety characteristics, which we discuss in our responses to comments 2 and 4 in this section of the final order.

(Comment 6) One commenter requested that FDA consider adding a requirement for human factors testing and/or a labeling comprehension study to the special controls.

(Response 6) FDA agrees with this comment. Based on literature and clinical data from other sources, FDA concurs that user compliance with the instructions for use is a significant factor in the effectiveness of these devices and maintaining user compliance is a known issue for these devices. These devices are used by patients, and the instructions for use should be clear and easy to follow. Additionally, labeling comprehension testing is currently relied upon to support PMA approvals of non-invasive bone growth stimulators. As such, we have added a special control to require labeling comprehension testing.

(Comment 7) One commenter stated that FDA should conduct premarket clinical and manufacturing inspections for these devices, even if they are reclassified from class III into class II.

(Response 7) FDA generally does not consider premarket clinical and manufacturing inspections to be necessary to provide reasonable assurance of safety and effectiveness for class II devices, including non-invasive bone growth stimulators. Preapproval inspections conducted in the context of a PMA approval allow FDA to assess the firm's capability to design and manufacture the device as claimed in the PMA and confirm that the firm's Quality Management System is in compliance with 21 CFR part 820, Quality Management System Regulation. FDA generally does not conduct similar premarket inspections for class II devices or when reviewing a 510(k).

Additionally, the hardware of these devices can generally be characterized with well-established methods and standards. The special controls identified in this final order establish requirements for validating both software and hardware components of these devices premarket, including that testing must verify and validate critical performance and safety characteristics of the device. The special controls also establish requirements relating to electromagnetic compatibility, electrical and thermal safety, biocompatibility, and software verification, validation, and hazard analysis.

For class II devices, routine and for cause inspections, which may consider compliance with quality management system requirements applicable to the manufacturing of the device, allow for appropriate postmarket oversight. Mechanisms and procedures for reporting safety concerns, such as MDRs and recalls, also provide additional postmarket surveillance to help ensure continued safety for marketed devices.

(Comment 8) One commenter requested that FDA either ''retain control over all postmarket [non-invasive bone growth stimulator] modifications'' through controls applicable to class III devices, or, if non-invasive bone growth stimulators are reclassified, that FDA include recommendations in guidance to explain which device modifications would be subject to premarket review. The commenter highlighted the importance of regulatory oversight of postmarket changes to ensure that device performance is not negatively impacted, noting that the 2006 Advisory Committee [14] and FDA previously recognized that device modifications that change device output may have unknown impacts on clinical response to treatment.

(Response 8) FDA disagrees that the requirements applicable to modifications of PMA-approved products (*i.e.,* premarket approval or annual reporting of changes as required for class III devices) are necessary for this device type. Consistent with 21 CFR 807.81(a)(3), a new 510(k) is required for any change or modification to a cleared device that could significantly affect the safety or effectiveness of the device, or for a major change or modification in intended use.[15] Changes and modifications that could significantly affect the safety or effectiveness of the device and may require a new 510(k) for

[14] The commenter is referring to a 2006 meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee, which considered a petition for reclassification of non-invasive bone growth stimulators. (See footnote 7 for additional information and references.)

[15] In accordance with 21 CFR 807.81(a)(3), a 510(k) is required for significant changes or modifications to a device including: (1) those that ''could significantly affect the safety or effectiveness of the device, *e.g.,* a significant change or modification in design, material, chemical composition, energy source, or manufacturing process''; or (2) a ''major change or modification in the intended use of the device.''

a non-invasive bone growth stimulator device include:

- Modifications of the therapeutic signal or modifications to the transducer such that there is change to the delivered therapeutic signal.
- Changes to the indicated patient population (age range, anatomic location, fracture or fusion type, etc.).

These examples are not exhaustive. Guidance on when device changes or modifications may require a new 510(k) can be found in ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' (Ref. 9) and ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device'' (Ref. 10).

Regardless of whether a new 510(k) is necessary, a modified device must continue to comply with the special controls. Additionally, manufacturers may wish to use predetermined change control plans (PCCPs) as a way to implement future modifications to their devices without needing to submit a new 510(k) for each significant change or modification [16] while continuing to provide reasonable assurance of device safety and effectiveness. [17] FDA reviews a PCCP as part of a marketing submission for a device to ensure the continued safety and effectiveness of the device without necessitating additional marketing submissions for implementing each modification described in the PCCP. When used appropriately, PCCPs authorized by FDA are expected to be least burdensome for manufacturers and FDA.[18]

IV. Changes in the Final Order

As described in sections II and III of this final order, FDA has made revisions in this final order in response to Panel feedback and comments submitted to the public docket on the proposed order (85 FR 49986).

Additionally, as noted in footnote 2, FDA has revised the identification language from the proposed order to add the phrase ''or as a treatment for established nonunions or failed fusions'' to the identification language codified in this final order. (See 21 CFR 890.5780(a)). This language was included in the proposed order as an indication presented to explain the intended use, but FDA has determined that for completeness it belongs in the identification language as part of the intended use. FDA has also moved the clause in the identification language that notes the device is only for prescription use from the second sentence of the identification to the first sentence of the identification. This change was made for consistency with other device types whose classification regulations fall into 21 CFR part 890. This change does not have any substantive effect.

Furthermore, in considering the revisions to the final order, FDA identified and added two additional risks to health: (i) use error or improper device use, and (ii) infection. While the labeling special control in the proposed order included cleaning instructions for reusable components, we recognize that adding the risk of infection clarifies the importance of validated cleaning instructions as a mitigation measure to address this risk to health. Accordingly, we updated the labeling special control to clarify that cleaning instructions must be validated. As discussed in our response to comment 6, FDA added a risk of use error or improper device use because user compliance with the instructions for use is a significant factor in the effectiveness of these devices and maintaining user compliance is a known issue for these devices. Accordingly, we added a special control to require that labeling comprehension testing must demonstrate the patient can correctly use the device based solely on reading the instructions for use.

Based in part on Panel feedback and comments on the proposed order, FDA revised the list of risks to health, the special controls that FDA determined will mitigate these risks, and Table 1, ''Risks to Health and Risk Mitigation Measures for Non-Invasive Bone Growth Stimulators''.

FDA has identified the following risks to health associated with the use of non-invasive bone growth stimulators:

- *Failure or delay of osteogenesis.* A patient could receive ineffective treatment, contributing to failure or delay of osteogenesis that may lead to clinical symptoms (*e.g.,* pain) and the need for surgical interventions. Ineffective treatment could be a result of various circumstances (*e.g.,* inadequate therapeutic signal output or device malfunction).
- *Use error or improper device use.* Use error or improper device use may result from a device design that is difficult to operate and/or labeling that is difficult to comprehend, leading to misuse of the device resulting in patient harm or ineffective treatment.
- *Burn.* A patient or health care professional could be burned from the use and operation of the device. This could be a result of various circumstances including device malfunction (*e.g.,* electrical fault) or misuse of the device (*e.g.,* use while sleeping).
- *Electrical shock.* A patient or health care professional could be shocked from the use and operation of the device. This could be a result of various circumstances including device malfunction (*e.g.,* electrical fault) or misuse of the device (*e.g.,* use of alternating current source during treatment).
- *Electromagnetic interference (EMI).* A patient with electrically powered implanted devices (such as cardiac pacemakers, cardiac defibrillators, and neurostimulators) could experience harm due to device malfunction as a result of electromagnetic interference between the implanted device and the non-invasive bone growth stimulator. Electronically powered devices in the environment (such as radiofrequency emitting household electrical equipment), may similarly interfere with the non-invasive bone growth stimulator device.
- *Adverse tissue reaction.* A patient could experience skin irritation and/or allergic reaction associated with the use and operation of the device via the use of non-biocompatible device materials.
- *Infection.* A patient could experience an infection if the patient-contacting components are not properly cleaned between uses.
- *Adverse interaction with internal/external fixation devices.* The signal output could be impacted by certain metallic internal or external fixation devices leading to inadequate treatment signals, device malfunction, or tissue heating and damage as a result of heating of the fixation device.
- *Adverse biologic effects.* A patient may experience adverse biologic effects resulting from prolonged exposure to the treatment signal via biologic interaction with the treatment signal at a cellular level. This could be due to various factors such as ultrasonic heating or tissue cavitation, excessive electrical current which could damage

[16] For the purpose of this final order reference to ''modification'' means a significant change or modification that would generally require a new premarket notification under 21 CFR 807.81(a)(3).

[17] Section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Public Law 117–328 (''FDORA''), enacted on December 29, 2022, added section 515C ''Predetermined Change Control Plans for Devices'' to the FD&C Act. Section 515C has provisions regarding PCCPs for devices requiring premarket approval or premarket notification. Under section 515C, supplemental applications (section 515C(a)) and new premarket notifications (section 515C(b)) are not required for a change to a device that would otherwise require a premarket approval supplement or new premarket notification if the change is consistent with a PCCP approved or cleared by FDA.

[18] Sections 513 and 515 of the FD&C Act. See also, FDA's guidance ''The Least Burdensome Provisions: Concept and Principles,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles.*

tissue, or electromagnetic fields which may interfere with biological function.

FDA has determined that the following special controls will mitigate these risks to health, and that these special controls, in addition to general controls, will provide a reasonable assurance of safety and effectiveness for non-invasive bone growth stimulators:

- The risk of failure or delay of osteogenesis can be mitigated by clinical data that demonstrates that the device performs as intended under anticipated conditions of use, including imaging data to demonstrate fusion at the treatment site. This risk can also be mitigated by non-clinical performance testing which additionally demonstrates that the device performs as intended under anticipated conditions of use, specifically through verification and validation of critical performance characteristics of the device. These include ensuring delivery of intended design outputs to the patient, thermal safety and reliability, the signal characteristics are within safe physiologic limits, and reliability of the device is consistent over the expected use-life. Software verification, validation, and hazard analysis will also help mitigate the risk of failure or delay of osteogenesis by ensuring that any device software performs as intended. Finally, labeling will also mitigate this risk by providing appropriate instructions for use (*e.g.,* duration, frequency of use) to the end user.
- The risk of use error or improper device use can be mitigated through labeling, including adequate warnings and instructions for use, and labeling comprehension testing that demonstrates the patient can correctly use the device based solely on reading the instructions for use.
- The risk of burns can be mitigated by non-clinical performance testing of the device to verify and validate critical performance characteristics, which include ensuring thermal safety and reliability, signal characteristics are within safe physiologic limits, and reliability of the device is consistent with its expected use-life. The risk of burns can be further mitigated by electrical safety testing to minimize the risk of thermal burns to the patient, and specific instructions regarding proper usage and specific warnings associated with the risk of burns.
- The risk of electrical shock can be mitigated by electrical safety testing to minimize the risk of shock to the patient. This risk can be further mitigated by labeling that includes instructions on appropriate usage and maintenance, and specific warnings regarding electrical shock.
- The risk of EMI can be mitigated through performance testing that demonstrates the EMC of the device and labeling to minimize the risk of adverse interaction with other electronic devices, such as implanted electronic devices.
- The risk of adverse tissue reaction can be mitigated by a biocompatibility evaluation to ensure that the materials used in patient-contacting components of the device are safe for skin contact and labeling that includes warnings against use on compromised skin or when there are known skin sensitivities, as well as validated instructions on appropriate cleaning of any reusable components.
- The risk of infection can be mitigated by labeling that includes validated instructions for appropriate cleaning of any reusable components.
- The risk of adverse interaction with internal/external fixation devices can be mitigated through labeling that includes appropriate warnings for patients with implanted medical devices, as well as non-clinical performance testing, which would include an evaluation of thermal safety and thermal reliability.
- The risk of adverse biologic effects can be mitigated by non-clinical performance testing to verify and validate critical performance characteristics of the device, which include ensuring thermal safety and reliability, signal characteristics are within safe physiologic limits, and reliability of the device over the expected use-life. The risk of adverse biological effects is further mitigated by software verification, validation, and hazard analysis, which will help ensure the device operates as intended.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR NON-INVASIVE BONE GROWTH STIMULATORS

Identified risk to health	Mitigation measures
Failure or delay of osteogenesis	Clinical performance data. Non-clinical performance testing. Software verification, validation, and hazard analysis. Labeling.
Use error or improper device use	Labeling comprehension testing. Labeling.
Burn	Non-clinical performance testing. Electrical safety testing. Labeling.
Electrical shock	Electrical safety testing. Labeling.
Electromagnetic interference	Electromagnetic compatibility (EMC) testing. Labeling.
Adverse tissue reaction	Biocompatibility evaluation. Labeling.
Infection	Labeling.
Adverse interaction with internal/external fixation devices	Non-clinical performance testing. Labeling.
Adverse biological effects	Non-clinical performance testing. Software verification, validation, and hazard analysis.

V. The Final Order

In this final order, FDA is adopting relevant findings from the August 17, 2020, proposed order (85 FR 49986). FDA has made revisions in this final order in response to the Panel deliberations (see section II) and comments received (see section III). FDA is issuing this final order to reclassify non-invasive bone growth stimulators from class III into class II under a new device classification regulation with the name non-invasive bone growth stimulator, and to establish special controls by revising 21 CFR part

890 (adding 21 CFR 890.5870). The identification for § 890.5870(a) has been revised from the proposed order to provide a more accurate description of the devices in this classification regulation.

Further, in this final order, FDA has identified the special controls under section 513(b)(1)(B) of the FD&C Act that, along with general controls, provide a reasonable assurance of the safety and effectiveness for non-invasive bone growth stimulators. In this final order, the Agency has made refinements to the special controls as previously described in the proposed order to further mitigate the risks to health associated with the use of non-invasive bone growth stimulators. Specifically, and among other things, FDA revised certain special controls for clarity, added imaging criteria to demonstrate effectiveness, and added a new special control for labeling comprehension. The clinical data special control now includes a requirement for imaging to demonstrate fusion at the treatment site as evidence that the device performs as intended. There is a new special control for labeling comprehension testing to demonstrate that patients can correctly use the devices based solely on the instructions for use. We made other minor revisions to several of the special controls for clarity.

Under the FD&C Act, 510(k)s are required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m).[19] FDA has not made this determination for non-invasive bone growth stimulators and, therefore, this class II device type is not exempt from 510(k) requirements. Thus, under sections 510(k) and 513(f) of the FD&C Act, persons who intend to market this device type must submit a 510(k) containing information on non-invasive bone growth stimulators that they intend to market and must obtain FDA clearance of the device prior to marketing.

Under this final order, non-invasive bone growth stimulators are prescription use devices under § 801.109 (21 CFR 801.109). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of § 801.109 are met. The device would continue to be subject to the submission and device clearance requirements of sections 510(k) and 513 of the FD&C Act and of part 807, subpart E of FDA's regulations (21 CFR part 807).

VI. Effective Date

This final order is effective 30 days after the date of its publication in the **Federal Register**.

VII. Analysis of Environmental Impact

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

VIII. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in FDA regulations. The previously approved 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 807, subpart E (Premarket Notification Procedures), have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 (Quality Management System Regulation) have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 (Investigational Device Exemptions) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through E (Premarket Approval of Medical Devices), have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 (Device Labeling) have been approved under OMB control number 0910–0485.

IX. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. In accordance with section 513(f)(3) of the FD&C Act, we are codifying in this final order the classification of non-invasive bone growth stimulators in the new 21 CFR 890.5870, under which these devices are reclassified from class III into class II.

X. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this final order, please note that websites are subject to change over time.

* 1. FDA, Sept. 8–9, 2020, Meeting of the Orthopaedic and Rehabilitation Devices Panel, Meeting Materials: *https://www.fda.gov/advisory-committees/advisory-committee-calendar/september-8-9-2020-orthopaedic-and-rehabilitation-devices-panel-medical-devices-advisory-committee.*

2. International Electrotechnical Commission, IEC 60601–1–2 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests, 2014. (Available at: *https://webstore.iec.ch/en/publication/2590.*)

* 3. FDA, Sept. 8, 2020, Meeting of the Orthopaedic and Rehabilitation Devices Panel Transcript: *https://www.fda.gov/media/145159/download.*

* 4. FDA, P190030 Summary of Safety and Effectiveness Data, December 9, 2020. (Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190030.*)

* 5. FDA, P210035 Summary of Safety and Effectiveness Data, May 3, 2022. (Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210035.*)

* 6. FDA, P230025 Summary of Safety and Effectiveness Data, February 9, 2024. (Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P230025.*)

[19] In considering whether to exempt class II devices from premarket notification, FDA considers whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA generally considers the factors initially identified in 63 FR 3142 (January 21, 1998) and further explained in FDA's guidance ''Procedures for Class II Device Exemptions from Premarket Notification,'' available at *www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff,* to determine whether premarket notification is necessary for class II devices. FDA also considers that even when exempting devices from the 510(k) requirements, these devices would still be subject to certain limitations on exemptions, for example, the general limitations set forth in 21 CFR 890.9.

* 7. FDA, P210016 Summary of Safety and Effectiveness Data, January 17, 2025. (Available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P210016*.)
* 8. FDA, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Guidance for Industry and FDA Staff,'' May 29, 2025. (Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program*.)
* 9. FDA, ''Deciding When to Submit a 510(k) for a Change to an Existing Device; Guidance for Industry and Food and Drug Administration Staff,'' October 25, 2017. (Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device*.)
* 10. FDA, ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device; Guidance for Industry and Food and Drug Staff,'' October 25, 2017. (Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device*.)

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.,* as amended) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for part 890 continues to read as follows:

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

■ 2. Add § 890.5870 to subpart F to read as follows:

§ 890.5870 Non-invasive bone growth stimulator.

(a) *Identification.* A non-invasive bone growth stimulator is a prescription device that provides stimulation through electrical, magnetic, or ultrasonic fields. The device is intended to be used externally to promote osteogenesis as an adjunct to primary treatments for fracture fixation and spinal fusion or as a treatment for established nonunions or failed fusions.

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

(1) Clinical data must demonstrate that the device performs as intended under anticipated conditions of use. Imaging data must demonstrate fusion at the treatment site.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Critical performance and safety characteristics of the device, considering the operational modality of the device, must be verified and validated to ensure:

(i) Intended design outputs are delivered to the patient;

(ii) Thermal safety and thermal reliability;

(iii) Signal characteristics are within safe physiologic limits; and

(iv) Device reliability is consistent with the expected use-life.

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

(4) Performance data must demonstrate the electrical safety and electromagnetic compatibility of the device.

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

(6) Labeling comprehension testing must demonstrate the patient can correctly use the device based solely on reading the instructions for use.

(7) Labeling for the device must include the following:

(i) Warning against use on compromised skin or when there are known skin sensitivities;

(ii) Appropriate warnings for patients with implanted medical devices;

(iii) A detailed summary of the supporting clinical data, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device;

(iv) A clear description of the device;

(v) Instructions on appropriate usage, duration, and frequency of use;

(vi) Instructions for maintenance and safe disposal;

(vii) Validated instructions for appropriate cleaning of any reusable components;

(viii) Specific warnings regarding user burns, electrical shock, and skin irritation; and

(ix) The risks and benefits associated with use of the device when used as intended.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07366 Filed 4–15–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

31 CFR Part 1010

Imposition of Special Measure Prohibiting Certain Transmittals of Funds Involving CIBanco S.A., Institución de Banca Multiple; Amendment

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Order; amendment of order.

SUMMARY: FinCEN is issuing notice of an order amending its June 2025 order finding that CIBanco S.A., Institución de Banca Multiple (CIBanco), is a financial institution operating outside of the United States that is of primary money laundering concern in connection with illicit opioid trafficking and imposing a special measure prohibiting certain transmittals of funds involving CIBanco. This amendment allows for certain transmittals of funds to facilitate payments necessary for the Government of Mexico to liquidate CIBanco.

DATES: FinCEN is amending the order published at 90 FR 27770 (June 30, 2025), as amended by 90 FR 30826 (July 11, 2025) and 90 FR 40974 (August 22, 2025), as of April 16, 2026.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at *http://www.fincen.gov/contact.*

SUPPLEMENTARY INFORMATION:

I. Statutory Authority

In 2024, Congress enacted the FEND Off Fentanyl Act,[1] which, among other things, added 21 U.S.C. 2313a [2] (section 2313a). Section 2313a grants the Secretary of the Treasury (Secretary) the authority to make a finding that ''reasonable grounds exist for concluding'' that any of the following is of primary money laundering concern in connection with illicit opioid trafficking:

(1) One or more financial institutions operating outside of the United States;

(2) One or more classes of transactions within, or involving, a jurisdiction outside of the United States; or

(3) One or more types of accounts within, or involving, a jurisdiction outside of the United States.[3]

Upon making such a finding, the Secretary is authorized to require

[1] The FEND Off Fentanyl Act is Division E of Public Law 118–50 (Apr. 24, 2024).

[2] Section 2313a codifies section 7213A of the Fentanyl Sanctions Act, as amended by section 3201(a) of the FEND Off Fentanyl Act. The Fentanyl Sanctions Act is Title LXXII of Public Law 116–92 (Dec. 20, 2019).

[3] 21 U.S.C. 2313a(a).