received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by establishing Class E airspace, extending upward from 700 feet above the surface, at Benton Field Airport. This area is designed to contain IFR departures to 1,200 feet above the surface and IFR arrivals descending below 1,500 feet above the surface. This airspace area would be described as follows: That airspace extending upward from 700 feet above the surface within a 3.3-mile radius of the airport, and within 4 miles east and 2.3 miles west of the 002° bearing from the airport, extending from 2.5 miles north of the airport to 12.4 miles north of the airport, and within 2.7 miles each side of the 176° bearing from the airport, extending from the 3.3-mile radius to 10.8 miles south of Benton Field Airport.

Class E5 airspace designations are published in paragraph 6005 of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial, and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP CA E5 Redding, CA

Benton Field Airport, CA
(Lat. 40°34′25″ N, long. 122°24′26″ W)

That airspace extending upward from 700 feet above the surface within a 3.3-mile radius of the airport, and within 4 miles east and 2.3 miles west of the 002° bearing from the airport, extending from 2.5 miles north of the airport to 12.4 miles north of the airport, and within 2.7 miles each side of the 176° bearing from the airport, extending from the 3.3-mile radius to 10.8 miles south of Benton Field Airport.

Issued in Seattle, Washington, on August 10, 2020.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2020–17875 Filed 8–14–20; 8:45 am]

BILLING CODE 4910–13–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, Health and Human Services (HHS).

ACTION: Proposed amendment; proposed order; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify non-invasive bone growth stimulators, postamendments class III devices (product codes LOF and LPQ), into class II (special controls), subject to premarket notification. FDA is also proposing a new device classification with the name ''non-invasive bone growth stimulators'' along with the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of these devices. FDA is proposing this reclassification on its own initiative. If finalized, this order will reclassify these devices from class III (premarket approval) to class II (special controls) and reduce the regulatory burdens associated with these devices, as these devices will no longer be required to submit a premarket approval application (PMA), but are subject to premarket notification (510(k)) requirements and general and special controls.

DATES: Submit either electronic or written comments on the proposed order by October 16, 2020. Please see section XII of this document for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. Electronic comments must be submitted on or before October 16, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 16, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1053 for ''Physical Medicine Devices; Reclassification of Non-Invasive Bone Growth Stimulators.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jesse Muir, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4508, Silver Spring, MD 20993, 240–402–6679, *Jesse.Muir@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

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 categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (general controls and special controls), and class III (general controls and premarket approval).

Devices that were not in 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) FDA 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 by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807), subpart E, of the regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by administrative order, can reclassify the device into class I or class 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 proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously presented before the Agency is an appropriate basis for subsequent action, where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 388–391 (D.D.C. 1991)) or in light of changes in ''medical science'' (*Upjohn* v. *Finch,* 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the ''new information'' to support reclassification under 513(f)(3) must be ''valid scientific evidence'', as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.

1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2), in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending 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 provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved (Ref. 1). This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

In accordance with section 513(f)(3) of the FD&C Act, FDA is issuing this proposed order to reclassify non-invasive bone growth stimulator devices, postamendments class III devices, into class II (special controls), subject to premarket notification because FDA believes the standard in section 513(a)(1)(B) of the FD&C Act is met as there is sufficient information to establish special controls, which in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.[1]

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to reasonably assure the safety and effectiveness of non-invasive bone growth stimulator devices. Therefore, the Agency does not intend to exempt these proposed class II devices from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

[1] In December 2019, FDA began adding the term ''Proposed amendment'' to the ''ACTION'' caption for these documents, typically styled ''Proposed order'', to indicate that they ''propose to amend'' the Code of Federal Regulations. This editorial 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.

II. Regulatory History of Non-Invasive Bone Growth Stimulator Devices

In accordance with section 513(f)(1) of the FD&C Act, non-invasive bone growth stimulator devices were automatically classified into class III because they were not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and have not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently classified or reclassified into class II or class I. Therefore, the device is subject to PMA requirements under section 515 of the FD&C Act (21 U.S.C. 360e).

Accordingly, on November 6, 1979, FDA approved a PMA for the Bio Osteogen System 204 (P790002) (Ref. 2). Since that time, five additional original PMAs have been approved for non-invasive bone growth stimulators (P850007, P850022, P900009, P910066, and P030034). On February 9, 2005, FDA received a reclassification petition dated February 7, 2005, submitted by RS Medical Corporation, requesting that FDA reclassify certain non-invasive bone growth stimulators from class III to class II (Ref. 3). As stated in the Notice of Panel Recommendation discussed further below, ''the petition was submitted under section 513(e) of the act but FDA . . . review[ed] the petition under section 513(f)(3) of the act because that section contain[ed] the appropriate procedures for reclassification of postamendments devices'' (72 FR 1951 at 1952, January 17, 2007). FDA requested additional information and the petitioner amended the petition on November 30, 2005 (''amended petition''). In accordance with the FD&C Act and regulations, FDA referred the petition, as amended, to the FDA Advisory Committee, specifically the Orthopaedic and Rehabilitation Devices Panel (''the 2006 Panel'') for its recommendations on the requested reclassification.

On June 2, 2006, the 2006 Panel deliberated on the information in RS Medical's petition; the presentations made by RS Medical, FDA, and members of the public; and their own experience with certain non-invasive bone growth stimulators (Ref. 4).

The 2006 Panel identified the following risks to health associated with non-invasive bone growth stimulators: Electric shock; burn; skin irritation and/or allergic reaction; inconsistent or ineffective treatment; adverse interaction with electrical implants; adverse interactions with internal/external fixation devices; and biological risks. The 2006 Panel did not specifically address risks associated with ultrasound-based devices, as these were outside the scope of RS Medical's petition; however, as discussed below, based upon FDA's review of information since the Panel meeting, the risks identified with ultrasound-based devices, along with their reported benefits, are comparable to those of non-invasive bone growth stimulators incorporating other modalities.

The majority of the 2006 Panel recommended that non-invasive bone growth stimulators should be retained in class III because there was insufficient information in the petition by RS Medical to establish that special controls in conjunction with general controls would provide a reasonable assurance of the safety and effectiveness of the device. Specifically, the Panel recommended that the proposed special controls by RS Medical were sufficient to control for the risk of electric shock, burn, skin irritation, and/or allergic reaction; adverse interaction with electrical implants; adverse interactions with internal/external fixation devices; and biological risks. However, the Panel believed that there was insufficient evidence presented by RS Medical to control for the risk of inconsistent or ineffective treatment because there is a lack of knowledge about how waveform characteristics (*e.g.,* pulse duration, amplitude, power, frequency), including potential modifications to the device, affect the clinical response to treatment. The Panel requested additional clinical data and/or special controls, which was not adequately devised by the petitioner, to control for the risk of inconsistent or ineffective treatment.

FDA concurred with the 2006 Panel's recommendation, and similarly believed that RS Medical's petition was inadequate in that FDA had concerns about the petitioner's proposed special controls to control the risk of inconsistent or ineffective treatment. In the **Federal Register** of January 17, 2007 (72 FR 1951), FDA published a Notice of Panel Recommendations (''the 2007 Notice''), as referenced above.

In a letter dated April 2, 2007, RS Medical requested that its petition be withdrawn (Ref. 5). On July 10, 2007, FDA granted RS Medical's request for withdrawal of the petition and did not take any further action on the petition (Ref. 6). FDA has not received any subsequent petition requesting reclassification of these devices.

Subsequently, as part of the Center for Devices and Radiological Health's 2014–2015 strategic priority, ''Strike the Right Balance Between Premarket and Postmarket Data Collection,'' a

retrospective review of all PMA product codes with active PMAs approved prior to 2010 was conducted to determine whether, based on our current understanding of the technology, certain devices could be reclassified (down-classified). On April 29, 2015, FDA published a document in the **Federal Register** identifying certain product codes as potential candidates for reclassification (80 FR 23798), including non-invasive bone growth stimulators under product codes LOF and LPQ, from class III to class II (Ref. 7). One comment was received in response to this proposal for reclassification of LOF and LPQ; this comment did not support FDA's intention to reclassify these devices, citing the concerns discussed during the 2006 Panel. This comment was considered in development of this proposed order. Note that invasive bone growth stimulators, designated under product code LOE, are outside the scope of this proposed reclassification. As noted in the 2006 Panel, invasive bone growth stimulator devices have added risks compared to non-invasive bone growth stimulators, and therefore would require a separate classification discussion. Furthermore, invasive bone growth stimulators were also considered as a part of the aforementioned PMA retrospective review and FDA determined that these devices should remain as class III (Ref. 8). Therefore, FDA will continue to regulate invasive bone growth stimulators as a class III device, subject to PMA requirements.

While RS Medical's petition inadequately addressed all of the risks associated with non-invasive bone growth stimulators for reclassification, FDA is, on its own initiative, proposing to reclassify these devices from class III to class II, and believes that sufficient information exists to establish special controls, as identified in this proposed order, that, together with general controls, can provide a reasonable assurance of safety and effectiveness for this device type. Additionally, RS Medical in its petition excluded use of these devices as an adjunct to cervical fusion surgery in patients at high risk for nonfusion, as well as for use in congenital pseudarthrosis. Based upon the review of the evidence and FDA's ability to establish special controls, FDA believes these indications that have been approved for currently marketed non-invasive bone growth stimulator devices should be included in this proposed reclassification.

III. Device Description

Non-invasive bone growth simulators, currently designated under product codes LOF and LPQ, are typically composed of a waveform generator and transducer (*e.g.,* coils, electrodes, and/or ultrasound transducers). Patient-contacting surfaces include the transducers, lead wires, and the device outer casing.

Non-invasive bone growth stimulators utilize an electrical component to produce an output electrical, magnetic, or ultrasonic waveform that is delivered to a treatment site via a non-invasively applied transducer (*e.g.,* electromagnetic coil or ultrasound transducer) or electrodes (*e.g.,* capacitor plates). The device also incorporates an internal means to monitor the output waveform and delivery of treatment, and to provide visual and/or audible alarms to alert the user of improper device function. The induced electrical and/or magnetic fields are generated using one of the following modalities:

- Capacitive coupling (CC), in which a pair of electrodes are placed on the skin such that a current can be driven across the target site;
- pulsed electromagnetic fields (PEMF), in which a modulated electromagnetic field is generated near the treatment site though an external coil; or
- combined magnetic fields (CMF), in which a coil generates a combination of a static and pulsed magnetic field near the treatment site.

The ultrasonic waveform is generated using:

- Low intensity pulsed ultrasound (LIPUS), in which pulsed ultrasonic signals are generated using ultrasonic transducers.

The non-invasive nature of the device obviates the need for sterile components; however, patient-contacting surfaces should be capable of being cleaned as needed and biocompatibility must be ensured.

Non-invasive bone growth stimulators are generally intended to promote osteogenesis as adjunct to primary treatments for fracture fixation or spinal fusion. The indications for use for this device type depend on the specific device characteristics, but have included:

- Treatment of an established non-union secondary to trauma of the appendicular system,
- treatment of congenital pseudarthrosis,
- treatment of failed fusions of the appendicular system,
- early treatment of certain fresh fractures, and
- as an adjunct to lumbar or cervical spinal fusion.

In addition, non-invasive bone growth stimulators are currently prescription use only devices under § 801.109 (21 CFR 801.109).

IV. Proposed Reclassification

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify non-invasive bone growth stimulator devices under product codes LOF and LPQ from class III into class II. This includes devices that generate electrical or magnetic fields using CC, PEMF, and CMF, and ultrasonic signals.

FDA believes that there is sufficient information available by way of FDA's accumulated experience with these devices from review of premarket submissions, peer-reviewed literature, medical device reports (MDRs), and recalls to understand the risks associated with these devices to establish special controls that effectively mitigate the risks to health identified in section V. In this proposed order, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, would provide a reasonable assurance of the safety and effectiveness for non-invasive bone growth stimulators to be in class II. Absent the special controls identified in this proposed order, general controls applicable to this device type are insufficient to provide reasonable assurance of safety and effectiveness of the device.

FDA is proposing to create a classification regulation for non-invasive bone growth stimulators, which would include devices designated under product codes LOF and LPQ. Under this proposed order, if finalized, a non-invasive bone growth stimulator will be identified as a prescription device. As such, the prescription device must satisfy prescription labeling requirements (see § 801.109, *Prescription devices*). 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. In this proposed order, if finalized, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, will provide a reasonable assurance of the safety and effectiveness for non-invasive bone growth stimulator devices.

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) of the FD&C Act if FDA determines that premarket notification is not necessary

to provide reasonable assurance of the safety and effectiveness of the device. For non-invasive bone growth stimulators, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, FDA does not propose to exempt these proposed class II devices from 510(k) requirements. If this order is finalized, persons who intend to market this type of device would need to submit to FDA a 510(k) and receive clearance prior to marketing the device.

V. Risks to Health

Based on available information for non-invasive bone growth stimulators, including the 2005 reclassification petition request from RS Medical Corp, input from the 2006 Panel, data in PMA applications P030034, P850022/S009, and P910066/S011 available to FDA under section 520(h)(4) of the FD&C Act, published literature, and postmarket experience associated with use of these devices, FDA identifies the following risks to health associated with non-invasive bone growth stimulators:

a. *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 or misuse).

b. *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).

c. *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).

d. *Electromagnetic interference (EMI)*—A patient with electrically powered implants (such as cardiac pacemakers, cardiac defibrillators, and neurostimulators) could experience an adverse interaction with the implanted electrical device via EMI or radiofrequency interference.

e. *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.

f. *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 damage.

g. *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. Excessive energy transmission could cause tissue damage or aberrant tissue behavior if signal output parameters exceed established safety thresholds.

The risks to health identified within this proposed order are consistent with those identified in the 2005 reclassification petition, as amended. The 2006 Panel agreed with these identified risks; however, in some cases the risk or accompanying description was reworded for clarity in this proposed order (*e.g.,* ''inconsistent treatment or ineffective treatment'' is described in terms of risk to health, which may entail ''failure or delay in osteogenesis''). Also, the risk of adverse biologic effects previously specified risks of carcinogenicity, genotoxicity, mutagenicity, and teratological effects. The petitioner notes in the amended petition that ''. . . the evidence points to lack of genotoxic, carcinogenic, and teratologic potential of the subject waveforms,'' which is corroborated by the lack of such reports identified in the literature. Although FDA similarly has found a lack of such reports, it considers this risk more generally as potential deleterious effects at the tissue or cellular level due to signal output parameters that exceed established safety thresholds.

VI. Summary of Reasons for Reclassification

FDA believes that non-invasive bone growth stimulator devices, which are intended to promote osteogenesis as an adjunct to primary treatments for fracture fixation or spinal fusion, should be reclassified from class III to class II and that there is sufficient information to establish special controls for the risks identified in section V which, in addition to general controls, can provide reasonable assurance of safety and effectiveness.

Specifically, FDA proposes to require clinical performance data as a special control to address the risk of failure or delay of osteogenesis. FDA review of the literature suggests a high variability of treatment efficacy, depending on therapeutic signal and anatomic location. This would also address the main concern cited by the 2006 Panel and FDA with RS Medical's proposal, which led to the recommendation to retain non-invasive bone growth stimulators in class III, and various comments received in response to the 2007 Notice.

FDA's proposal would require that clinical performance of any non-invasive bone growth stimulator device be evaluated in support of the intended use. Rather than prescribe specific study requirements, FDA's proposal would allow for flexibility in study design and the level of clinical evidence needed by taking into consideration certain parameters, *e.g.,* the intended use, treatment population, and technological characteristics of the device, including any similarities between the device and legally marketed predicate device, as appropriate.

VII. Summary of Data Upon Which the Reclassification Is Based

The available evidence demonstrates that there are probable health benefits derived from the use of these devices, and that the nature and incidence of risks are well known so that special controls can be established to adequately mitigate the risks to health. FDA is proposing a single device class for non-invasive bone growth stimulators, considering that FDA did not identify any unique risks associated with the different modalities included in this proposed order. FDA has considered and analyzed the following: Data in PMA applications P030034, P850022/S009, and P910066/S011 available to FDA under section 520(h)(4) of the FD&C Act; information presented at the 2006 Panel concerning RS Medical's petition to down-classify certain non-invasive bone growth stimulators (Ref. 3) and the 2007 Notice; peer-reviewed articles that discussed the use of, as well as the probable benefits and risks of these devices; reported adverse events identified through a search of FDA's Medical Device Reporting (MDR) system; and a review of any recalls associated with these devices through a search of FDA's Medical Device Recall database.

In accordance with the ''6-year rule'' described in section 520(h)(4) of the FD&C Act, FDA considered data contained in three original PMAs or supplements, P030034, P850022/S009, and P910066/S011, approved for non-invasive bone growth stimulators (Refs. 9 to 11). These PMAs/supplements include three different device modalities: A PEMF device (P030034), a CC device (P850022/S009), and a CMF device (P910066/S011). In review of the reported clinical data in the summary of

safety and effectiveness data documents (SSEDs), the studies conducted in support of these devices include a total study size of 831 enrolled subjects. The adverse event profile for the devices in each study were similar to the control group, with a similar distribution of event types. With regards to benefit, the clinical data reported in the SSEDs demonstrate an improved rate of bone fusion compared to placebo controls, with an 83.6 percent vs. 68.6 percent fusion rate at 6 months in P030034 (cervical spine), an 85 percent vs. 75 percent clinical success shown in P850022/S009 (lumbar spine), and a 67 percent vs. 43 percent fusion rate at 9 months in P910066/S011 (lumbar spine).

Further, FDA performed a literature review to evaluate data related to non-invasive bone growth stimulator devices, including studies up to the date of the 2006 Panel, as well as any new clinical information published since the 2006 Panel.

Literature published at the time of the 2006 Panel includes a 1953 seminal paper on the use of electrical signals to stimulate bone formation by Yasuda, that reported bone formation in rabbits exposed to direct current (DC) stimulation (Ref. 12). In the following decades, other researchers expanded on this finding in animal and clinical models. In a canine study, a DC stimulation was shown to cause complete ossification of the femoral medullary canal (Ref. 13). The first clinical case report demonstrated that electrical stimulation could treat a non-union fracture (Ref. 14). An early publication regarding the effects of DC stimulation on spinal fusion was published by Dwyer (Ref. 15). Another early clinical study published by Becker, et al. showed successful fracture fusion with a success rate of 77 percent (Ref. 16).

In the 1990s and early 2000s, several literature articles were identified assessing the effects of non-invasive bone growth stimulators on various anatomic locations. These studies generally included various therapeutic modalities (magnitude, frequency, duration, etc.) and demonstrated varying results regarding the efficacy of these treatments. In two studies of PEMF devices, Basset and Schink-Ascani (Ref. 17) found a 72 percent fusion rate in patients with congenital pseudarthrosis of the tibia, and in a study of non-unions of the scaphoid, Adams, et al. (Ref. 18) reported a fusion rate of 69 percent, as a followup to an earlier study that found a fusion rate of 80 percent. When looking at the rate of compliance of PEMF devices as a factor of effectiveness, Garland, et al. (Ref. 19) found that fusion rates ranged from 35.7 percent to 80 percent, depending on how often the devices were used. In studies of CC devices, fusion rates in long bones varied from 60 percent (Ref. 20), 68.8 percent (Ref. 21), and 72.7 percent (Ref. 22), to no difference between treatment and a placebo-treated group in a study by Fourie and Bowerbank (Ref. 23). While there was a large range of observed efficacies, there was no reporting of treatment-related adverse events. These reported variabilities in efficacy and low adverse event rates were consistent with the findings by the 2006 Panel.

FDA performed a systematic review of published literature to identify any new clinical findings since the 2006 Panel. FDA identified 14 papers that included a combination of retrospective and prospective studies. For studies that assessed medical or insurance claims databases, radiographs were not always available to determine actual fusion. Instead, results were presented in terms of *healing rate* based on patient records or reported outcomes. When radiographs were available and analyzed to assess union, results were reported as *fusion rate.*

Phillips, et al. (Ref. 24) looked at registry data of 2,370 subjects who were treated with OL1000 (DJO), a CMF device, at various fracture sites and reported an average healing rate of 75.1 percent (ranging from 57.2 percent in the humerus to 89.7 percent in the finger phalanx). DeVries, et al. (Ref. 25) also evaluated the OL1000 device in a retrospective analysis of 144 subjects, finding a fusion rate of 57.1 percent in tibiotalocalcaneal fusions of the ankle.

With respect to LIPUS, Zura, et al. (Refs. 26 and 27) published two papers evaluating subjects in the Exogen (Bioventus) Post Market Registry. One of the studies assessed how various patient risk factors affected healing rate in 4,190 subjects. The study demonstrated an overall healing rate of 95.7 percent, and in another single arm study of 767 subjects, showed a healing rate varying from 81.8 percent to 87.9 percent depending on fracture site. Nolte, et al. (Ref. 28) evaluated the Exogen registry in conjunction with a medical claims database to examine metatarsal fractures and reported a healing rate of 97.4 percent overall, while Elvey, et al. (Ref. 29) evaluated 26 cases with use of Exogen in hand and wrist non-unions, and found a fusion rate of 54 percent to 58 percent. In two smaller studies of the Exogen device, Majeed, et al. (Ref. 30) and Mizra, et al. (Ref. 31) both evaluated foot and ankle fractures and found 78.7 percent and 67 percent fusion rate in a 47 and 18 patient study, respectively. Biglari (Ref. 32) also performed an observational study using the Exogen device and found a much lower fusion rate of 32.8 percent in 60 subjects having existing non-unions of various long bones.

For PEMF devices, a retrospective study by Coric, et al. (Ref. 33) on the effects of the CervicalStim (Orthofix) device on 593 subjects showed a 73.2 percent fusion rate in the cervical spine at 6 months. In a single arm prospective study by Assiotis, et al. (Ref. 34), a 77.3 percent fusion rate in the tibia was demonstrated with use of the Physiostim (Orthofix). Murray and Pethica (Ref. 35) performed a 1,382-subject retrospective study of use of the EBI device (Zimmer Biomet) for non-unions of the scaphoid, tibia, and fibula, and while an assessment of healing rates was not performed, the data showed reduction in time to healing between 35 percent and 40 percent when the device was used as prescribed.

In addition, two randomized control studies on PEMF devices were conducted by Foley, et al. (Ref. 36) and by Streit, et al. (Ref. 37). Foley evaluated 323 subjects using the Orthofix CervicalStim device in cervical fusion and found an 83.6 percent fusion rate in the treatment group compared to a 68.6 percent fusion rate in the control group, with no difference in pain scores or adverse events between groups. Streit, et al. performed a small, eight subject clinical study using the EBI device to treat non-unions of the fifth metatarsal and found the time to fusion was reduced on average from 14.7 weeks to 8.9 weeks with the use of the device.

In summary, FDA's literature review resulted in findings that are consistent with available clinical data from PMA submissions. These studies suggest that there are probable benefits to the use of these devices; however, differences in methodology, including differences in devices used, treatment waveform and frequency, patient populations, as well as anatomic location, could have had significant effects on reported device effectiveness, which ranged from 32.8 percent to 97.4 percent. Regarding safety, the findings from these studies demonstrate that the devices are relatively safe as the adverse event profile associated with these devices using various modalities was similar to controls. Overall, the studies involved 10,566 subjects (including control subjects), with only a single report of a serious adverse event (Biglari, Ref. 32); however, a direct link to the use of the device could not be established for this event.

Further, a search of FDA's MDR database was conducted to identify all adverse events submitted to FDA up to October 31, 2019, for devices approved under product codes LOF and LPQ. The results of the identified reports are consistent with the risk profiles identified in both PMA applications and literature that were reviewed. FDA's search yielded a total of 270 unique MDRs. The most frequently reported events were categorized as ''skin reaction/issue'' (n = 187) followed by ''pain'' (n = 59) and ''device functional issue'' (n = 21). A review of the adverse events regarding skin reactions found that a majority were due to irritation from the electrode adhesive or ultrasound gel used. There was no apparent difference in risk profile across the various device modalities, though the risk of skin irritation was primarily observed in the skin-contacting devices (due to the electrodes in the CC device and the gel in the LIPUS device). For cases where followup was described, patients recovered when treatment was discontinued. In addition, 11 reports of ''mass/tumor'' were identified; however, the nature of the relationship between the mass/tumor to the device was unrelated or unclear. Based upon FDA's assessment of other systematic reviews of these devices, no other reports of mass/tumors have been identified (Refs. 38 to 42).

Finally, a search of FDA's Medical Device Recall database was conducted. No recalls were found when searching the database for devices under product code LOF. Two class 2 recalls were reported for devices under product code LPQ; specifically, there was a recall for the Exogen Express Bone Healing System and a recall for the Exogen 4000+ Ultrasound Bone Healing System. Both were posted on August 4, 2009, and initiated by the manufacturer because of problems with the transducer, which may have resulted in a reduced ultrasound output. These recalls were terminated on November 18, 2010. These recall events reflect the risks to health identified in section V, and FDA believes the special controls proposed, in addition to general controls, can effectively mitigate the risks identified.

VIII. Proposed Special Controls

Table 1 outlines the risks to health identified in section V and the corresponding mitigation measures proposed to reasonably assure safety and effectiveness, which are discussed in more detail below.

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.
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.
Adverse interaction with internal/external fixation devices	Labeling.
Adverse biological effects	Non-clinical performance testing. Software verification, validation, and hazard analysis.

The risk of failure or delay of osteogenesis is clinically significant. To mitigate this risk, FDA proposes that manufacturers provide clinical performance data to demonstrate that the device yields positive outcomes (*e.g.,* fusion of the non-union) in accordance with its intended use. Further, FDA proposes non-clinical performance testing to demonstrate that the device performs as intended under anticipated conditions of use to achieve the identified successful clinical performance characteristics. This would include verification and validation of critical performance characteristics, including characterization of the designed outputs of the device as well as the outputs that are delivered to the patient, thermal safety and reliability testing, reliability testing consistent with the expected device use-life, and validation that signal characteristics are within safe physiologic limits. Also, FDA proposes appropriate software verification, validation, and hazard analysis to ensure that any device software performs as intended. Lastly, FDA proposes labeling to provide appropriate instructions (*e.g.,* duration, frequency of use) to the end user.

To mitigate the risk of skin burns, FDA proposes non-clinical performance testing of the device to verify and validate critical performance characteristics, demonstrate thermal safety and reliability, validate that signal characteristics are within safe physiologic limits, and demonstrate reliability of the device consistent with its expected use-life. FDA also proposes 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.

To mitigate electrical shocks, FDA proposes electrical safety testing to minimize the risk of shock to the patient. Furthermore, FDA proposes labeling provisions, including instructions on appropriate usage and maintenance, and specific warnings regarding electrical shock.

To mitigate electromagnetic interference, FDA proposes electromagnetic compatibility testing and labeling to minimize the risk of adverse interaction with other electronic devices such as implanted electronic devices.

To mitigate the risk of adverse tissue reactions, FDA proposes 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 sensitivities, as well as instructions on appropriate cleaning of any reusable components.

To mitigate the risk of adverse interaction with internal/external fixation devices, FDA proposes labeling,

specifically inclusion of appropriate warnings for patients with implanted internal/external devices.

To mitigate the risk of adverse biologic effects, FDA proposes non-clinical performance testing to verify and validate critical performance characteristics of the device, demonstrate thermal safety and reliability, validate safety of the signal by reference to known biological safety limits, and demonstrate reliability of the device over the expected use-life. Furthermore, FDA proposes software verification, validation, and hazard analysis.

If this reclassification is finalized, non-invasive bone growth stimulators will be reclassified into class II and would be subject to premarket notification (510(k)) requirements under § 807.81. As discussed below, the intent is for the reclassification to be codified in 21 CFR 890.5870. Firms submitting a 510(k) for non-invasive bone growth stimulators will be required to comply with the particular mitigation measures set forth in the special controls. Adherence to the special controls, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of these devices.

IX. 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.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. This proposed order refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XI. 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. Therefore, under section 513(f)(3), in the proposed order, we are proposing to codify non-invasive bone growth stimulators in the new 21 CFR 890.5870, under which non-invasive bone growth stimulators would be reclassified from class III to class II.

XII. Proposed Effective Date

FDA proposes that any final order based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

XIII. 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 also are 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. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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2. *P790002 Approval available at: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P790002.*

3. *RS Medical Corporation Reclassification Petition, available at *https://wayback.archive-it.org/7993/20170405072021/https://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4224b1-06-TabB-RSMEDICAL-Petition.pdf.*

4. *FDA's Orthopaedic and Rehabilitation Devices Panel transcript and other meeting materials for the June 2, 2006, meeting are available at: *https://wayback.archive-it.org/7993/20170403222246/https://www.fda.gov/ohrms/dockets/ac/cdrh06.html#orthopaedic.*

5. *Letter from RS Medical requesting withdrawal of petition, available at *https://www.regulations.gov/document?D=FDA-2005-P-0052-0007.*

6. *FDA letter granting RS Medical's withdrawal request, available at *https://www.regulations.gov/document?D=FDA-2005-P-0052-0006.*

7. *First Cohort of Results of the 2014–2015 Strategic Priority: Strike the Right Balance Between Premarket and Postmarket Data Collection (April 2015), available at *https://www.fda.gov/media/91437/download.*

8. *Second and Final Cohort of Results of the 2014–2015 Strategic Priority: Strike the Right Balance Between Premarket and Postmarket Data Collection (August 2016), available at *https://www.fda.gov/media/99822/download.*

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List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 890 be 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 provides stimulation through electrical, magnetic, or ultrasonic fields. The device is for prescription use and is intended to be used externally to promote osteogenesis as an adjunct to primary treatments for fracture fixation or spinal fusion.

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

(1) Clinical performance data must support the intended use of the device.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be provided:

(i) Verification and validation of critical performance characteristics of the device, including characterization of the designed outputs of the device as well as the outputs that are delivered to the patient.

(ii) Thermal safety and thermal reliability testing.

(iii) Validation that signal characteristics are within safe physiologic limits.

(iv) Reliability testing consistent with the expected use-life of the device.

(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 for the device must include the following:

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

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

(iii) A detailed summary of the clinical testing, 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) 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.

Dated: August 4, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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