engines installed on the same airplane at the same time, if at all possible.

Alternative Methods of Compliance

(i) The Manager, Engine Certification Office, FAA, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(j) GE Service Bulletin No. CF34–10E S/B 73–0013, dated December 15, 2006, pertains to the subject of this AD.

(k) Contact Tara Fitzgerald, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7138, fax (781) 238–7199; e-mail: *tara.fitzgerald@faa.gov* for more information about this AD.

Issued in Burlington, Massachusetts, on January 10, 2007.

Francis A. Favara,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E7–498 Filed 1–16–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 2005P–0121]

Orthopedic Devices; Reclassification of Non-Invasive Bone Growth Stimulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment the recommendation of the Orthopaedic and Rehabilitation Devices Panel to deny a petition to reclassify the non-invasive bone growth stimulator from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by RS Medical Corp., as well as consideration of presentations made at the Panel meeting by the petitioner, FDA, and members of the public. FDA is also issuing for public comment its findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**.

DATES: Submit written or electronic comments by April 17, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2005P–0121, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. 2005P–0121 for this notice. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michel Janda, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3600.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on 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 (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Reclassification of classified postamendments devices is governed by section 513(f)(3) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for

reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. The Panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

In accordance with section 513(f)(1) of the act, the non-invasive bone growth stimulators 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 can not be placed in commercial distribution unless it is reclassified under section 513(f)(3), or subject to an approved premarket approval application (PMA) under section 515 of the act (21 U.S.C. 360e).

In a petition dated February 7, 2005, that was received by FDA on February 9, 2005, RS Medical Corp. requested that FDA reclassify the non-invasive bone growth stimulator from class III to class II. (Ref. 1) The petition was submitted under section 513(e) of the act but FDA is reviewing the petition under section 513(f)(3) of the act because that section contains the appropriate procedures for reclassification of postamendments devices. FDA requested additional information and the petitioner amended the petition on August 1, 2005. In accordance with the act and the regulations, FDA referred the petition as amended to an FDA Advisory Committee, the Orthopedic and Rehabilitation Devices Panel (the Panel) for its recommendations on the requested reclassification.

III. Description of Device Proposed for Reclassification

The Petitioner identified the device as follows:

A non-invasive bone growth stimulator is a device that provides stimulation through electrical and/or magnetic fields to facilitate the healing of nonunion fractures and lumbar spinal fusions. The stimulation may be delivered through capacitive coupling (CC) with electrodes placed directly over the treatment site or through pulsed electromagnetic fields (PEMF) with treatment coils placed into a brace or over a cast at the treatment site. The device is intended for use: (1) For the treatment of established nonunion fractures acquired secondary to trauma (excluding vertebrae and flat bone), and (2) as an adjunct to the treatment of lumbar spinal fusion surgery for one or two levels. The device consists of an output waveform generator, either battery-powered or AC-powered; a user interface with visual and/or audible alarms; and electrodes or coils to deliver the stimulation.

IV. Recommendations of the Panel

On June 2, 2006, the Panel deliberated on information in RS Medical's petition; the presentations made by RS Medical, FDA, and members of the public; and their own experience with non-invasive bone growth stimulators (Ref. 2). The Panel voted four to two to recommend that non-invasive bone growth stimulators be retained in class III.

V. Risks to Health

The Panel identified the following risks to health associated with the non-invasive bone growth stimulator:

A. Electric Shock

A patient or health care professional could be shocked from the use and operation of the device via an AC line voltage exposure during charging, circuitry malfunction, connection/disconnection of electrodes or coils, control circuit failure, damaged channel jacks, defective electrodes/coil delivering inappropriate output, faulty lead wires, inappropriate output, poor connection between electrodes/coils and lead wires, poor solder on circuit board, reposition of electrodes/coils during treatment, and use of AC current source during treatment.

B. Burn

A patient or health care professional could be burned from the use and operation of the device via an AC line voltage exposure during charging, connection/disconnection of the electrodes/coils or control unit while receiving treatment, defective electrodes/coil delivering inappropriate output, incorrect electrode/coil size or alteration, inappropriate output, use of AC current source for treatment, and use of control unit and battery charger while sleeping.

C. Skin Irritation and/or Allergic 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 and/or non-biocompatible electrode gel.

D. Inconsistent or Ineffective Treatment

A patient could receive inconsistent or ineffective treatment via battery deterioration, control circuit failure, defective electrode/coils, device damage from dropping or bumping, device short circuits, driver circuit failure, electromagnetic interference (EMI) or radio frequency interference (RFI), failure to follow prescribed use, hardware failure, improper position of electrodes/coil, inappropriate output, incorrect battery/battery charger, ineffective output, low battery voltage, poor interface between electrodes/coil and patient, and switch failure.

E. Adverse Interaction with Electrical Implants

A patient with electrically-powered implants (such as cardiac pacemakers, cardiac defibrillators, and neuro-stimulators) could experience an adverse interaction with an implanted electrical device via EMI or RFI.

F. Internal/External Fixation Devices

A patient with internal or external fixation devices could receive inconsistent or ineffective treatment due to interaction of the device with the metallic fixation devices via interference with treatment field through magnetic field interaction and/or electrical inductance within metallic device.

G. Biological Risks: Carcinogenicity, Genotoxicity, Mutagenicity, and Teratology

A patient may experience adverse biologic affects resulting from prolonged exposure to the treatment signal via biologic interaction with the treatment signal at a cellular level.

VI. Summary of Reasons for Recommendation

The Panel believes that the non-invasive bone growth stimulator should be retained in class III because there is insufficient information in this petition

to establish that special controls in association with general controls would provide a reasonable assurance of the safety and effectiveness of the device.

VII. Summary of Data Upon Which the Panel Recommendation is Based

The petitioner provided the following information:

A. Reports on Non-Unions

The petitioner submitted 35 articles (5 describing capacitive coupling devices and 30 describing the use of pulsed electromagnetic field devices) reporting outcomes for over 5,600 patients. According to the petitioner, these studies indicate the device's ability to promote osteogenesis in patients with an established non-union, which may include previously failed surgical attempts to establish union.

B. Reports on Adjunctive Lumbar Spinal Fusion

The petitioner has submitted eight articles (one utilizing capacitive coupling devices and seven utilizing pulsed electromagnetic field devices) reporting outcomes for over 1,100 patients. According to the petitioner, these studies indicate the device's ability to promote osteogenesis in patients as an adjunct to the treatment of lumbar spinal fusion for one or two levels.

C. Reports on Preclinical Findings

The petitioner has cited 21 articles in the petition amendment describing studies in animal models. The animal studies described in the petition amendment were designed to evaluate new signals, dose/response relationships, and the potential pathways of bone repair processes. In addition, 14 articles were presented that describe studies in cell culture systems designed to examine the mechanism(s) of action of various electrical stimuli in bone. These studies, conducted at the cellular level, were intended to investigate the sequence of events that occur as a result of electrical stimulation, the interaction of the fields at the level of the cell membrane with regard to ion channels and receptor interaction, and signal transduction; and to identify cell types that do or do not respond to electrical stimulation.

The Panel recommended that the proposed special controls (Ref 1.) were sufficient to control for the risk of electric shock, burn, skin irritation, and/or allergic reaction; adverse interaction with electrical implants; adverse interaction with internal/external fixation devices; and biological risks (carcinogenicity, genotoxicity, mutagenicity and teratology). However, the Panel believed that there was insufficient evidence presented by the petitioner 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) affect the clinical response to treatment. This concern was also expressed by the Panel regarding potential modifications made to the device. It is not known how a change to the device output due to device modifications may impact the clinical response to treatment. The Panel requested additional clinical data and/or special controls to control for the risk of inconsistent or ineffective treatment that may occur as the result of device modifications (Ref. 2).

VIII. FDA's Findings

FDA believes that certain device modifications are unlikely to adversely affect device safety and effectiveness and such changes could be adequately validated using bench-top testing. However, FDA also believes that there was not adequate evidence in the petition to establish that the petitioner's proposed special controls could be used to adequately mitigate the risk of inconsistent or ineffective treatment. Additional evidence is required to establish special controls, including preclinical test methods, to mitigate the risk of inconsistent or ineffective treatment.

Because FDA has concerns about the ability of the petitioner's proposed special controls to control the risk of inconsistent and ineffective treatment, FDA is unable to conclude that general controls and the petitioner's proposed special controls would provide a reasonable assurance of safety and effectiveness for this device type. Therefore, based on the currently available information, FDA concurs with the Panel's recommendation to retain the non-invasive bone growth stimulator as a class III device.

IX. 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. Analysis of Impacts

FDA has examined the impacts of this notice under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this reclassification petition denial, if finalized, is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. If FDA accepts the Panel recommendation and denies the petition for reclassification, the regulatory status of the device will remain the same as it is now. Because this action, if finalized, will maintain the status quo, the agency certifies that the reclassification petition denial will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this reclassification petition action to result in any 1-year expenditure that would meet or exceed this amount.

XI. Federalism

FDA has analyzed this action in accordance with the principles set forth in Executive Order 13132. FDA has determined that the action, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the action does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this notice. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Reclassification petition from RS Medical Corp., dated February 7, 2005, and amendment dated November 30, 2005.

2. Orthopedic and Rehabilitation Devices Panel Meeting Transcript, June 2, 2006.

Dated: January 5, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–476 Filed 1–16–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 292

RIN 1076–AE81

Gaming on Trust Lands Acquired After October 17, 1988

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: This document reopens the comment period for the proposed rule published on December 4, 2006 (71 FR 70335), which establishes procedures that an Indian tribe must follow in seeking to conduct gaming on lands acquired after October 17, 1988.

DATES: Comments must be received on or before February 1, 2007.

ADDRESSES: You may submit comments identified by the number 1076–AE81, by any of the following methods:

- *Federal rulemaking portal*: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax*: 202–273–3153.
- *Mail*: Mr. George Skibine, Director, Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, 1849 C Street, NW., Mail Stop 3657–MIB, Washington, DC 20240.
- *Hand Delivery*: Office of Indian Gaming, Office of the Deputy Assistant Secretary—Policy and Economic Development, 1849 C Street, NW., Mail Stop 3657–MIB, Washington, DC, from 9 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: George Skibine, Office of Indian Gaming, Acting Deputy Assistant Secretary—Policy and Economic Development, Mail Stop 3657–MIB, 1849 C Street, NW., Washington, DC 20240; Telephone (202) 219–4066.

SUPPLEMENTARY INFORMATION: On October 5, 2006 (71 FR 58769), the Bureau of Indian Affairs (BIA) published a proposed rule to establish procedures that an Indian tribe must follow in seeking to conduct gaming on lands acquired after October 17, 1988. The Indian Gaming Regulatory Act allows Indian tribes to conduct class II and class III gaming activities on land acquired after October 17, 1988, only if the land meets certain exceptions. This proposed rule establishes a process for submitting and considering applications from Indian tribes seeking to conduct class II or class III gaming activities on lands acquired in trust after October 17, 1988.

On December 4, 2006, the BIA published a notice making corrections to the proposed rule and extended the comment period until December 19, 2006. Eighteen comments were received after December 19, 2006. Several of these comments raise substantive issues that may result in modification of the proposed rule. The comment period is reopened to allow consideration of the comments received after December 19, 2006, and to allow additional time for comment on the proposed rule. Comments must be received on or before February 1, 2007.

Dated: January 11, 2007.

Michael D. Olsen,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. E7–511 Filed 1–16–07; 8:45 am]

BILLING CODE 4310–4N–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2005–KY–0004–200609; FRL–8269–4]

Approval and Promulgation of Implementation Plans; Kentucky: Performance Testing and Open Burning

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Kentucky State Implementation Plan (SIP), submitted by the Commonwealth of Kentucky, through the Kentucky Department of Air Quality (KDAQ), on September 6, 2005. The revisions include changes to Kentucky Administrative Regulations (KAR) Title 401, Chapters 50:045, ''Performance tests,'' and 63:005, ''Open burning.'' The changes included in the proposed SIP revisions are part of Kentucky's strategy to attain and maintain the 8-hour ozone and fine particulate ($PM_{2.5}$) national ambient air quality standards (NAAQS) by reducing emissions of $PM_{2.5}$ and precursors to ozone. EPA is proposing to approve Kentucky's SIP revisions pursuant to section 110 of the Clean Air Act (CAA).

DATES: Written comments must be received on or before February 16, 2007.

ADDRESSES: Submit your comments, identified by Docket ID Number, ''EPA–R04–OAR–2005–KY–0004,'' by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. E-mail: *hou.james@epa.gov*.
3. Fax: 404–562–9019.
4. Mail: ''EPA–R04–OAR–2005–KY–0004,'' Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.
5. Hand Delivery or Courier: James Hou, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID Number, ''EPA–R04–OAR–