Dated: August 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–0788]

Neurological Devices; Reclassification of the Totally Implanted Spinal Cord Stimulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is announcing for public comment the recommendation of the Neurological Devices Panel (the Panel) to reclassify the totally implanted spinal cord stimulator (SCS) for treatment of chronic intractable pain of the trunk or limbs from class III into class II. The Panel made this recommendation after reviewing the reclassification petition submitted by Advanced Neuromodulation Systems, Inc. (ANS), and other publicly available information. FDA is also announcing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.''

DATES: Submit written comments by October 6, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Russell P. Pagano, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1296.

SUPPLEMENTARY INFORMATION:

I. Background

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 (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (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 1976 amendments enactment date), 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. A postamendment device remains in class III and requires premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device 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 previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act. This section allows FDA to initiate reclassification of a postamendments class III device 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 § 860.134 (21 CFR 860.134) set forth the procedures for the filing and review of a petition for reclassification of such class III devices. 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)(2)(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

The totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs is a postamendments device classified into class III under section 513(f)(2) of the act. Therefore, the device cannot be placed in commercial distribution for treatment of chronic intractable pain of the trunk or limbs unless it is reclassified under section 513(f)(2) of the act, or subject to an approved PMA under section 515 of the act.

This action is taken in accordance with section 513(f)(2) of the act and § 860.134 of the regulations, based on information in the ANS petition submitted on June 16, 1999. ANS requested reclassification of totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs from class III into class II. Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested reclassification.

III. Device Description

The following device description is based on the Panel's recommendations and the agency's review: The totally implanted SCS consists of an implanted

pulse generator (IPG), leads, and electrodes. The IPG contains the internal power source that is implanted in the patient. The electrodes are placed on the patient's spinal cord and the leads from the electrodes are connected subcutaneously to the IPG.

IV. Recommendation of the Panel

At a public meeting on September 16 and 17, 1999, the Panel recommended that the totally implanted SCS intended for aid in the treatment of chronic intractable pain of the trunk or limbs be reclassified from class III into class II.

V. Risks to Health

After considering the information in the petition, the information presented at the Panel meeting, the Panel's deliberations, the published literature, and the Medical Device Reports (MDR's), FDA has evaluated the risks to health associated with the use of the totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs. FDA now believes that the following are risks to health associated with use of the device: Lead migration, device failure, tissue reaction, skin erosion, surgical procedural risks, lack of electromagnetic compatibility (EMC), and lack of magnetic resonance (MR) compatibility.

A. Lead Migration

Lead migration is the movement of the lead from its intended position (Ref. 1). It can result in a change in stimulation and a subsequent reduction in pain relief. Lead migration may require reoperation to adjust or replace the leads or may require stimulator reprogramming.

B. Device Failure

Device failure, including battery failure, lead breakage, hardware malfunction, and loose connections can lessen or eliminate stimulation and can result in ineffective pain control. Battery failure requires reoperation to replace the battery in the IPG component of the device (Ref. 1). The life of the battery in the totally implanted SCS is affected by the following factors: Battery type, output characteristics of the stimulator (i.e., voltage, pulse rate, pulse width, and frequency), number of electrodes used, and duration of use. Replacement of the battery earlier than the expected date is considered a battery failure. In addition, a damaged or improperly sealed IPG case can also result in battery leakage that could potentially cause tissue damage, as well as device failure.

C. Tissue Reaction

Adverse tissue reaction due in part to biocompatibility concerns is a potential risk to health associated with all implanted devices (Ref. 1). In addition, changes in stimulation can occur due to changes in the tissue surrounding the electrodes. Suboptimal stimulation can result in ineffective pain control.

D. Skin Erosion

Skin erosion over the IPG is a potential risk to health associated with use of the device. When skin erosion is attributed to the IPG, the device is usually explanted (Ref. 1).

E. Surgical Procedural Risks

Temporary pain at the implantation site is expected in any implant surgery.

Infection is a risk to health associated with all surgical procedures and implanted devices (Ref. 1). The best defenses against infection are preventive measures, including selection of patients without known local and/or systematic infection, administration of perioperative antibiotics, implantation of a sterile device, and strict adherence to sterile surgical technique.

Cerebrospinal fluid (CSF) leakage is also a potential risk to health and can cause a severe headache, which usually occurs in the early postoperative period. CSF leakage can occur from accidental dural puncture by an epidural needle, guide wire, or the leads during the surgical procedure. The headache may be frontal or occipital, and it may be accompanied by tinnitus, diplopia, neck pain, and nausea. A post procedural headache may be treated with injection of autologous blood into the patient's epidural space if conservative measures are unsuccessful (Ref. 1).

Although rare, epidural hemorrhage, seroma, hematoma, and paralysis are potential risks to health associated with totally implanted SCS (Ref. 1).

F. EMC

External sources of electromagnetic interference may cause the device to malfunction and the stimulation parameters to change. This suboptimal stimulation can result in ineffective pain control or an increase in stimulation resulting in induced pain.

G. MR Compatibilty

If the device is not designed to be compatible with magnetic resonance procedures, various adverse consequences could result. First, a needed imaging study may not be able to be performed, and second, if a MR procedure is performed, the results may be compromised by the device artifact or the device itself may be adversely affected (e.g., movement and/or heating).

VI. Summary of Reasons for Recommendation

The Panel believed that the device should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

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

The Panel based its recommendations on the information contained in the petition, information provided by FDA, and their personal knowledge of the device. In addition to information concerning the potential risks associated with the use of the totally implanted SCS device described in section V of this document, there is reasonable knowledge of the benefits of the device (Refs. 1 and 2). Specifically, the device can provide pain relief resulting in an overall improved quality of patient life.

VIII. Special Controls

FDA believes that the draft guidance document special control identified below, in addition to general controls, is sufficient to control the identified risks to health for this device. FDA agrees with the Panel that FDA guidances are appropriate special controls to provide reasonable assurance of the safety and effectiveness of the device. However, FDA disagrees with the Panel that consensus standards, postmarket surveillance, preclearance manufacturing inspections, device tracking, and patient registries are necessary special controls for the device.

A. Guidance Document

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief.''

The draft guidance document has sections on intended use and indications for use, device description, labeling, technological characteristics, testing, and manufacturing that control the risks to health associated with use of the device identified in section V of this document. The draft guidance document addresses the risks to health associated with the use of the device in the following ways:

1. The risk of lead migration is addressed by design controls under the Quality Systems Regulation. The labeling section of the draft guidance also ensures that there are adequate directions for implantation of the leads and that there is a warning about this risk to health.

2. The risk of device failure is also addressed by design controls under the Quality Systems Regulation. The labeling section in the draft guidance document also ensures that there are adequate directions for use, a battery life table, and shelf life information. It also addresses the warnings, precautions, and adverse effects statements related to device failure that should appear in the labeling.

3. The risk of tissue reaction is addressed in the testing section of the draft guidance document to ensure that the device materials and the finished device are biocompatible.

4. The risk of skin erosion is addressed in the labeling section of the draft guidance document to ensure that adequate directions for implantation of the device are provided in the labeling and that this risk is noted in the adverse effects statements of the labeling.

5. The risks common to the surgical procedure for implanting the device, temporary pain and infection, are addressed in the labeling section of the draft guidance document. As noted in section V.E of this document, infection may also be caused by implantation of a nonsterile device, as well as by nonsterile technique. The risk of infection from a nonsterile device is addressed in the testing and manufacturing section of the draft guidance document to ensure that the device is sterile. The potential risks of CSF leakage, epidural hemorrhage, seratoma, hematoma, and paralysis are addressed in the labeling section of the draft guidance by warning of these possible potential adverse effects in the device labeling.

6. The risks associated with EMC are addressed in the testing section of the draft guidance to ensure that the device's EMC is properly characterized. The labeling section of the draft guidance also states that appropriate warnings about EMC should be in the device's labeling.

7. The risks associated with MR are addressed in the testing section of the draft guidance to ensure that the device's MR compatibility is properly characterized. The labeling section of the draft guidance also states that appropriate warnings about MR compatibility should be in the device's labeling.

FDA believes that the draft guidance document addresses the Panel's recommendation for a guidance document special control.

B. Consensus Standards

The Panel recommended that consensus standards be a special control for the totally implanted SCS. The draft guidance document testing section references the use of biocompatibility, electrical, EMC, and packaging consensus standards to help provide reasonable assurance of the safety and effectiveness of the totally implanted SCS. An FDA guidance concerning device sterility is also referenced in the current guidance document. FDA believes that these sections in the guidance address the Panel's concern.

C. Postmarket Surveillance

The Panel stated that it was important that adverse device outcomes be tracked through postmarket surveillance. FDA agrees with the Panel that adverse device outcomes should be reported to FDA. However, FDA believes that the existing mandatory MDR system is the appropriate mechanism to report such adverse events. Therefore, additional postmarket surveillance is unnecessary to address the Panel's concerns to provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommended that annual reporting of battery failures to FDA would be an appropriate special control to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that the MDR system captures reporting of device malfunctions that could cause a serious injury, including battery failure. Therefore, FDA does not believe that annual reports of device failures should be a special control for the device.

D. Preclearance Manufacturing Inspections

The Panel also recommended that preclearance manufacturing inspections ''at the class III device level'' be a special control for the totally implanted SCS. FDA notes that the Quality System Regulation (QSR) (21 CFR part 820) that sets forth current good manufacturing practice requirements applies to all devices except certain devices exempted by regulation from the QSR. FDA also notes that there are no device class-related levels of QSR inspections. Prior to premarket approval of a class III device, FDA conducts a QSR inspection of the class III device manufacturing site as part of the premarket approval process. Class II device manufacturing sites are periodically inspected after FDA clears the device for marketing. The difference between QSR inspection of a class II manufacturing site and a class III device manufacturing site is the timing of the inspection and not the nature of the inspection. FDA believes that safety and effectiveness of the totally implanted SCS can be reasonably assured by the manufacturing section in the draft guidance document and by general controls applicable to all medical devices, including QSR inspections. Therefore, FDA does not think a QSR inspection prior to FDA marketing clearance is necessary to provide reasonable assurance of the safety and effectiveness of the totally implanted SCS.

E. Device Tracking

The Panel also recommended that device tracking be a special control for the device. Tracking is a compliance mechanism intended to facilitate notification and recall in the event of serious risks to health presented by a device. The totally implanted SCS does not meet the three criteria for a tracked device: (1) The likelihood of sudden catastrophic failure, (2) the likelihood of significant adverse clinical outcome, and (3) the need for prompt professional intervention. Therefore, FDA does not believe that device tracking is necessary to provide reasonable assurance of the safety and effectiveness of the device.

F. Patient Registries

The Panel also recommended patient registries be a special control for the totally implanted SCS. FDA notes that the use of patient registries is a type of postmarket surveillance to answer a particular question related to a device's performance or to track patients when particular clinical issues are identified. Neither the Panel nor FDA has identified a clinical issue requiring patient registries. Therefore, FDA does not believe that patient registries are necessary to provide reasonable assurance of the safety and effectiveness of the device.

IX. FDA's Tentative Findings

FDA believes that the totally implanted SCS intended for treatment of chronic intractable pain of the trunk or limbs should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance. FDA believes that the draft guidance document entitled ''Special Control Guidance for Premarket Notifications for Totally Implanted Spinal Cord Stimulators for Pain Relief''

is an appropriate special control to provide reasonable assurance of the safety and effectiveness of the device.

FDA notes that it has considered a comment from a manufacturer of a totally implanted SCS for pain relief and a comment from the petitioner after the September 16 and 17, 1999, Panel meeting in its formulation of these tentative findings. These comments have been placed in the docket referenced in the heading of this document.

X. References

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

1. Advanced Neuromodulation Systems, Inc., Plano, TX, Classification Proposal and Summary of Safety and Effectiveness Information for the Totally Implanted Spinal Cord Stimulator, received June 16, 1999.

2. Transcript of the September 16 and 17, 1999, Neurological Devices Panel Meeting, September 17, 1999, volume, pp. 153–284.

XI. 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.

XII. Analysis of Impacts

FDA has examined the impacts of the notice under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), 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 potential reclassification action is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this potential reclassification action is not a significant regulatory action as defined by the Executive Order and so is not subject to review under 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. Reclassification of the device from class III to class II will relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, 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 of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the reclassification action, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation.

XIII. Paperwork Reduction Act of 1995

FDA concludes that this reclassification action contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XIV. Federalism

FDA has analyzed this reclassification action in accordance with the principles set forth in Executive Order 13132. FDA has determined that the reclassification action does not contain policies that 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 has concluded that the action does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

XV. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this document by October 6, 2000. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 22, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–22618 Filed 9–5–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1485]

Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors; Notice of Availability; Public Meeting by Satellite

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability and announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report entitled ''Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors'' and a public meeting via an interactive satellite teleconference. The purpose of the meeting is to present: The methodology used for developing a baseline on the occurrence of the Centers for Disease Control and Prevention (CDC)-identified foodborne illness risk factors in retail-level institutional food establishments, restaurants, and retail food stores and the data from the baseline inspections that were conducted by FDA Regional Food Specialists in 1998 to 1999.

Date and Time: The meeting will be held on October 27, 2000, 1 p.m. to 4 p.m. Satellite coordinates for the broadcast will be posted on the FDA Internet at www.fda.gov beginning October 13, 2000. The report will be available beginning September 11, 2000, on the FDA Internet at www.fda.gov and hard copies will be available after October 1, 2000, from the contact persons listed below.

Location: The satellite meeting will be broadcast nationwide from the FDA broadcast studio at the Center for Devices and Radiological Health, 16071–B Industrial Dr., Gaithersburg, MD 20877.

Contact: Denise M. Buckmon or LaKesha P. Abbey, Office of Field