DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Jean-Yves Mignolet
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Re: K122566
Cefaly
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 882.5891
Regulation Name: Transcutaneous Electrical Nerve Stimulator to Treat Headache
Regulatory Classification: Class II
Product Code: PCC
Dated: December 13, 2012
Received: December 13, 2012

Dear Mr. Mignolet:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the Cefaly, a prescription device under 21 CFR Part 801.109 that is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Cefaly, and substantially equivalent devices of this generic type, into class II under the generic name, Transcutaneous Electrical Nerve Stimulator to Treat Headache.

FDA identifies this generic type of device as:

> **Transcutaneous Electrical Nerve Stimulator to Treat Headache.** A transcutaneous electrical nerve stimulator to treat headache is a device used to apply an electrical current to a patient's cranium through electrodes placed on the skin.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under

section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on November 20, 2012 automatically classifying the Cefaly in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On December 13, 2012, FDA received your *de novo* requesting classification of the Cefaly into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Cefaly into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Cefaly indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Adverse Reactions to skin-contacting materials	Biocompatibility Testing Labeling
Electrical, Mechanical, or Thermal Hazards that may result in user discomfort or injury	Electromagnetic Compatibility Testing Electrical, Mechanical, and Thermal Safety Testing Technical Parameters Electrode Performance Testing Software Verification, Validation and Hazard Analysis Labeling
Ineffective treatment	Clinical Performance Data Labeling
Failure to identify the correct population	Clinical Performance Data Labeling
Misuse that may result in user discomfort, injury, or delay treatment for headaches	Labeling

In combination with the general controls of the FD&C Act, the Transcutaneous Electrical Nerve Stimulator to Treat Headache is subject to the following special controls:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.

3. The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2000, and 10000 ohm loads), pulse duration, frequency, net charge (μC) per pulse, maximum phase charge at 500 ohms, maximum current density (mA/cm², r.m.s.), maximum average current (mA), maximum average power density (W/cm²), and the type of impedance monitoring system must be fully characterized.

4. Electrical performance, adhesive integrity, shelf-life, reusability, and current distribution testing of the electrodes must be conducted.

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

6. Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population.

7. Labeling must include the following:
    a. Appropriate contraindications such as not for use in subjects with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator.
    b. Appropriate warnings such as not to apply the device on the neck or chest, not to use the device in the presence of electronic monitoring equipment, not to use in the bath or shower, not to use while sleeping, not to use while driving, not to use while operating machinery..
    c. Appropriate precautions such as the long-term effects of chronic use of the device are unknown.
    d. A summary of the expected risks and benefits of using the device.
    e. A summary of the clinical performance data, including information on the patient population for which the device has and has not been demonstrated to be effective, and any adverse events and complications.
    f. Information on how the device operates and the typical sensations experienced during treatment.
    g. A detailed summary of the device technical parameters.
    h. An expiration date/shelf life for the electrodes and the number of times they can be reused.
    i. Disposal instructions.

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 type.

FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Transcutaneous Electrical Nerve Stimulator to Treat Headache they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact John Doucet, Ph.D. at (301) 796-6474.

Sincerely yours,

Jonette R. Foy -S

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