DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 14, 2016

Sensory Medical, Inc.
Fred Burbank, MD
1235 Puerta del Sol, #500
San Clemente, CA 92673

Re: DEN110011
Symphony Device (Models 09-0002-01, 09-0003-01, and 09-0004-01)
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.5895
Regulation Name: Vibratory counter-stimulation device
Regulatory Classification: Class II
Product Code: OVP
Dated: July 12, 2011
Received: July 13, 2011

Dear Dr. Burbank:

This letter corrects our classification order dated December 18, 2013.

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 *Symphony* Device, a prescription device under 21 CFR Part 801.109 that is indicated to improve the quality of sleep in patients with primary Restless Legs Syndrome (RLS) through the use of vibratory counter-stimulation. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the *Symphony* Device, and substantially equivalent devices of this generic type, into class II under the generic name, Vibratory counter-stimulation device.

FDA identifies this generic type of device as:

> **Vibratory counter-stimulation device.** A vibratory counter-stimulation device is a prescription device that provides electrically powered mechanical vibration to improve the quality of sleep in patients with primary Restless Legs Syndrome.

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 June 14, 2011 automatically classifying the *Symphony* Device 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 July 13, 2011, FDA received your *de novo* requesting classification of the *Symphony* Device into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the *Symphony* Device 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 *Symphony* Device indicated for improving the quality of sleep in patients with primary Restless Legs Syndrome (RLS) through the use of vibratory counter-stimulation 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 with the device type are summarized in Table 1.

Table 1 - Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Pain, discomfort, worsening of RLS symptoms	Non-clinical Testing Software Testing Labeling
Electrical shock	Electrical Safety Testing Labeling
Burns	Electrical and Thermal Safety Testing Labeling
Adverse skin reactions	Biocompatibility Assessment Labeling
Interference with other medical devices	Electromagnetic Compatibility Testing Labeling

In combination with the general controls of the FD&C Act, the Vibratory counter-stimulation device is subject to the following special controls:

1. Appropriate analysis/testing must demonstrate electromagnetic compatibility (EMC), electrical safety, and thermal safety.
2. If the device contains software or firmware, appropriate verification, validation, and hazard analysis must be performed.
3. The elements of the device that contact the patient must be assessed to be biocompatible.
4. Non-clinical testing data (including vibration frequency, amplitude and acceleration) must demonstrate that the device performs as intended under anticipated conditions of use.
5. Labeling must include:
    a. Specific information pertinent to use of the device by the intended patient population and the treatment regimen.
    b. Warning to only use the device on normal, intact, clean, healthy skin.
    c. Warning to not use the device if the user has leg skin disorders, such as eczema, psoriasis, cellulitis, non-healing wounds.
    d. Warning to discontinue use if restless leg syndrome symptoms worsen.
    e. Instructions for end users to contact the device manufacturer and MedWatch in case they experience any adverse events when using this device.

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. 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 Vibratory counter-stimulation device 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 FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C 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 Mr. Michael Hoffmann at (301)796-6476 or michael.hoffmann@fda.hhs.gov.

Sincerely,

William H. Maisel -S

William Maisel, M.D., M.P.H.
Deputy Director for Science and Chief Scientist
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