DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Brain Sentinel, Inc.
c/o Hrishikesh Gadagkar
Idonea Solutions, Inc.
7 Poplar Road
Chadds Ford, PA 19317

February 16, 2017

Re: DEN140033
Brain Sentinel Monitoring and Alerting System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.1580
Regulation Name: Non-EEG physiological signal based seizure monitoring system
Regulatory Classification: Class II
Product Code: POS
Dated: November 6, 2014
Received: November 10, 2014

Dear Mr. Gadagkar:

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 Brain Sentinel Monitoring and Alerting System, a prescription device under 21 CFR Part 801.109 that is indicated as follows:

> The Brain Sentinel Monitoring and Alerting System is indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The device is to be used on the belly of the biceps muscle to analyze surface electromyographs (sEMG) signals that may be associated with generalized tonic-clonic (GTC) seizures and to provide an alarm to alert caregivers of unilateral, appendicular, tonic extension that could be associated with a GTC seizure. The System records and stores sEMG data for subsequent review by a trained healthcare professional.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Brain Sentinel Monitoring and Alerting System, and substantially equivalent devices of this generic type, into class II under the generic name, Non-EEG physiological signal based seizure monitoring system.

FDA identifies this generic type of device as:

> N**on-EEG physiological signal based seizure monitoring system.** The non-electroencephalogram (non-EEG) seizure monitoring system is a non-invasive prescription

device that collects physiological signals other than EEG to identify physiological signals that may be associated with a seizure.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (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.

On November 10, 2014, FDA received your De Novo requesting classification of the Brain Sentinel Monitoring and Alerting System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Brain Sentinel Monitoring and Alerting System 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 Brain Sentinel Monitoring and Alerting System, indicated for use as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest, can be classified in class II with the establishment of special controls. 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 Method**
Adverse tissue reaction	Biocompatibility evaluation
Equipment malfunction leading to injury to users (shock, burn)	Electrical safety, thermal, and mechanical testing Electromagnetic compatibility testing Labeling
Interference with or from other electrical devices	Electromagnetic compatibility testing
Incorrect alerts, including : 1) Missing a seizure – device fails to identify physiological signal that is associated with a seizure; or 2) False alarm – device mistakenly	Clinical performance testing Non-clinical performance testing Software verification, validation and hazard analysis Labeling Training

Identified Risk	Mitigation Method
identifies a physiological signal as being associated with a seizure	

In combination with the general controls of the FD&C Act, the Non-EEG physiological signal based seizure monitoring system is subject to the following special controls:

1. The technical parameters of the device, hardware and software, must be fully characterized and include the following information:

    a. Hardware specifications must be provided. Appropriate verification, validation and hazard analysis must be performed.
    b. Software, including any proprietary algorithm(s) used by the device to achieve its intended use, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

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

3. The device must be designed and tested for electrical, thermal and mechanical safety and electromagnetic compatibility (EMC).

4. Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for monitoring for seizure related activity in the intended population and for the intended use setting. Performance measurements must include positive percent agreement (PPA) and false alarm rate (FAR).

5. Training must be provided for intended users that includes information regarding the proper use of the device and factors that may affect the collection of the physiologic data.

6. The labeling must include healthcare professional labeling and patient-caregiver labeling. The healthcare professional and the patient-caregiver labeling must include the following information:

    a. A detailed summary of the clinical performance testing, including any adverse events and complications.
    b. Any instructions technicians and clinicians should convey to patients and caregivers regarding the proper use of the device and factors that may affect the collection of the physiologic data.
    c. Instructions to technicians and clinicians regarding how to set the device threshold to achieve the intended performance of the 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.

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 Non-EEG physiological signal based seizure monitoring system 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 Xiaorui Tang, Ph.D. at 301-796-6500 or Xiaorui.Tang@fda.hhs.gov.

Sincerely yours,

Angela C. Krueger -A

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