DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 15, 2013

NEBA Health, LLC
Mr. E. Howard Merry
President
753 Broad Street, Suite 701
Augusta, GA 30901

Re: K112711
Neuropsychiatric EEG-Based Assessment Aid for ADHD (NEBA) System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.1440
Regulation Name: Neuropsychiatric Interpretive Electroencephalograph Assessment Aid.
Regulatory Classification: Class II
Product Code: NCG
Dated: December 7, 2011
Received: December 8, 2011

Dear Mr. Merry:

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 Neuropsychiatric EEG-Based Assessment Aid for Attention Deficit Hyperactivity Disorder (ADHD), referred to as the NEBA System, a prescription device under 21 CFR Part 801.109 that is indicated as follows:

> The Neuropsychiatric EEG-Based ADHD Assessment Aid (NEBA) uses the theta/beta ratio of the EEG measured at electrode CZ on a patient 6-17 years of age combined with a clinician's evaluation to aid in the diagnosis of ADHD.
>
> NEBA should only be used by a clinician as confirmatory support for a completed clinical evaluation or as support for the clinician's decision to pursue further testing following a clinical evaluation. The device is NOT to be used as a stand-alone in the evaluation or diagnosis of ADHD.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Neuropsychiatric EEG-Based Assessment Aid for ADHD (NEBA) System, and substantially equivalent devices of this generic type, into class II under the generic name, Neuropsychiatric Interpretive Electroencephalograph Assessment Aid.

FDA identifies this generic type of device as:

> **Neuropsychiatric Interpretive Electroencephalograph Assessment Aid.** The Neuropsychiatric Interpretive Electroencephalograph Assessment Aid is a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition. The Neuropsychiatric Interpretive EEG

Assessment Aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

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 18, 2011 automatically classifying the NEBA System 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 8, 2011, FDA received your *de novo* requesting classification of the NEBA System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NEBA 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 NEBA System, indicated for use as stated above, 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 Measures
Adverse Tissue Reaction	Biocompatibility Labeling
Electromagnetic Incompatibility	Electromagnetic Compatibility Testing
Equipment Malfunction Leading to Injury to User/Patient (shock, burn, or mechanical failure)	Electrical safety, thermal, and mechanical testing Labeling
False Result Leading to Delay in Treatment or Unnecessary Treatment due to Hardware Failure	Performance testing Hardware and Software verification, validation and hazard analysis Technical parameters Labeling
False Result due to Incorrect Artifact Reduction	Operator training Software verification and validation Labeling
False Result due to Incorrect Placement of Electrodes	Operator training Clinical performance testing Labeling
False Result when a Neuropsychiatric Interpretive EEG Assessment Aid is used for Confirmatory Support or Support for Further Testing	Clinical performance testing Device design characteristics Labeling
Use error	Clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the Neuropsychiatric Interpretive Electroencephalograph Assessment Aid is subject to the following special controls:

1. The technical parameters of the device, hardware and software, must be fully characterized and must demonstrate a reasonable assurance of safety and effectiveness.
    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 arrive at its interpretation of the patient's condition, 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 device parts that contact the patient must be demonstrated to be biocompatible.

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

4. Clinical performance testing must demonstrate the accuracy, precision, reproducibility, of determining the EEG-based interpretation, including any specified equivocal zones (cut-offs).

5. Clinical performance testing must demonstrate the ability of the device to function as an assessment aid for the medical condition for which the device is indicated. Performance measures must demonstrate device performance characteristics per the intended use in the intended use environment. Performance measurements must include sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) per the device intended use. Repeatability of measurements must be demonstrated using interclass correlation coefficients and illustrated by qualitative scatter plot(s).

6. The device design must include safeguards to prevent use of the device as a stand-alone diagnostic.

7. The labeling must bear all information required for the safe and effective use of the device, including:
    a. A warning that the device is not to be used as a stand-alone diagnostic.
    b. A detailed summary of the clinical performance testing, including any adverse events and complications.
    c. The qualifications and training requirements for device users including technicians and clinicians.
    d. The intended use population and the intended use environment.
    e. Any instructions technicians should convey to patients regarding the collection of EEG data.
    f. Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.
    g. Where appropriate, validated methods and instructions for reprocessing of any reusable components.

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 Neuropsychiatric Interpretive Electroencephalograph Assessment Aid they intend to market prior to marketing the device and receive clearance to market from FDA.

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 Peter G. Como, Ph.D. at 301-796-6919.

Sincerely yours,

Jonette R. Foy -S

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