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

Auguat 1, 2016

Jan Medical, Inc.
c/o Jan McComb, Ph.D.
ICRC, Inc.
22515 Aspan Street, Suite F
Lake Forest, California 92630

Re: DEN140040
BrainPulse, Model 1100
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 882.1630
Regulation Name: Cranial Motion Measurement Device
Regulatory Classification: Class II
Product Code: POP
Dated: December 19, 2014
Received: December 23, 2014

Dear Dr. McComb:

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 BrainPulse, Model 1100, a prescription device under 21 CFR Part 801.109 that is indicated as follows:

> "*The BrainPulse is intended for use on a patient's head to non-invasively detect, amplify and capture the skull motion caused by pulsatile flow from the cardiac cycle. The BrainPulse is not indicated to aid in the diagnosis of neurological conditions, diseases, or disorders.*"

FDA concludes that this device should be classified into class II. This order, therefore, classifies the BrainPulse, Model 1100, and substantially equivalent devices of this generic type, into class II under the generic name, Cranial Motion Measurement Device.

FDA identifies this generic type of device as:

> **Cranial Motion Measurement Device.** A cranial motion measurement device is a prescription device that utilizes accelerometers to measure the motion or acceleration of the skull. These measurements are not to be used for diagnostic purposes.

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 December 23, 2014, FDA received your *de novo* requesting classification of the BrainPulse, Model 1100 into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BrainPulse, Model 1100 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 BrainPulse, Model 1100 indicated for the following:

> "*The BrainPulse is intended for use on a patient's head to non-invasively detect, amplify and capture the skull motion caused by pulsatile flow from the cardiac cycle. The BrainPulse is not indicated to aid in the diagnosis of neurological conditions, diseases, or disorders.*"

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 Tissue Reaction	Biocompatibility Evaluation Labeling
Equipment Malfunction Leading to Injury to User or Patient	Electrical Safety, Thermal, and Mechanical Testing Electromagnetic Compatibility Testing Labeling
Inaccurate Measurement	Clinical Performance Testing Hardware and Software verification, validation and hazard analysis Electromagnetic Compatibility Testing Labeling
Use Error	Hardware and Software verification, validation and hazard analysis Labeling

In combination with the general controls of the FD&C Act, the Cranial Motion Measurement Device 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. Additionally, verification and validation testing as well as a hazard analysis must be performed.
    b. Software must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Additionally, software verification and validation testing as well as a 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, thermal and mechanical safety and electromagnetic compatibility (EMC).

4. Clinical performance testing must demonstrate the accuracy, precision, stability, and repeatability of measuring cranial motion per the intended use in the intended use environment.

5. The labeling must include:
    a. The intended use population and the intended use environment.
    b. Instructions for technicians to convey to patients regarding the collection of cranial acceleration data to ensure device measurement accuracy, precision, stability, and repeatability.
    c. Information allowing clinicians to understand potential sources of variability in the measurement to help recognize and identify changes in the measurement.

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 Cranial Motion Measurement 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 Jay Gupta at 301-796-2795.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and
Radiological Health