DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 28, 2017

Jan Medical, Inc.
Prabhu Raghavan
VP of Clinical, Quality and Regulatory
110 Pioneer Way, Suite L
Mountain View, California 94041

Re: K170926
Trade/Device Name: BrainPulse 1100
Regulation Number: 21 CFR 882.1630
Regulation Name: Cranial Motion Measurement Device
Regulatory Class: Class II
Product Code: POP
Dated: March 27, 2017
Received: March 29, 2017

Dear Mr. Raghavan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170926

Device Name
BrainPulse 1100

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

BrainPulse™ 1100

Date Prepared	March 27, 2017
Submission number	K170926
Company Name and Address	Jan Medical Inc. 110 Pioneer Way, Suite L Mountain View, California 94041 USA
Contact Person	Prabhu Raghavan Vice President of Clinical, Quality and Regulatory Phone: 1-650-316-8813 Fax: 1 650-316-8812
Device:	BrainPulse™ 1100
Trade Name:	BrainPulse
Predicate Device:	BrainPulse 1100 (de novo granted under DEN140040)
Regulation Number:	21 CFR 882.1630
Product Code:	POP
Common/Classification Name:	Cranial Motion Measurement Device
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Regulatory Class:	II
Intended Use:	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.

Device Description:

The BrainPulse™ 1100 is a non-invasive device having three basic components that are provided as an entire system and all are non-sterile and reusable:

- Headset with detachable cable that is patient contacting and includes:
  - One Photoplethysmograph (PPG) sensor for detecting the heart rate and timing;
  - One Sound Pressure Level (SPL) sensor for detecting ambient environment noise; and
  - Six Accelerometer sensors to detect the acceleration at six selected locations.
- Data Collector, which digitizes the analog signals from the headset
- Computer, which incorporates the device Software and space to store the BrainPulse recording data and,
- Device Software, which provides the user interface, hardware control software libraries

The BrainPulse collects and stores skull motion caused by pulsatile flow from the cardiac cycle. The normal brain structure produces a motion that is driven by and synchronized with the heart rate, and is manifested by slight acceleration of the skull. The device uses piezoelectric-based accelerometer sensors that measure skull motion rather than brain sounds. The typical frequencies that are employed with the BrainPulse are below 20 Hz and mostly below 10 Hz, well below the lower limit of audible sound.

The headset senses the motion and the Data Collector digitizes the signal. The computer mainly provides the user interface and stores the data for further processing. Users place the device's headset on patients and setup the user interface to perform a BrainPulse recording. Typically, a recording is about 2-3 minutes long, though users may obtain recordings up to 30 minutes long depending on their applications. Recordings may be obtained at any time.

Patient Contacting Materials of Use

LDPE (Low Density Poly Ethylene), PE (Poly Ethylene), PEEK (Polyether ether ketone) and Urethane

Substantial Equivalence:

The current submission is for the same device and model that was cleared by the agency in de novo, DEN140040. The only change is to the software user interface. The hardware is

	unchanged; it is the same hardware that was cleared in DEN140040. Software validation as well as system verification was performed to show equivalence to the previous software that was cleared in DEN140040. This validation and verification testing demonstrated that the device output is equivalent to the output of the previous device version.
Changes to Predicate Device:	The device hardware elements are unchanged, i.e., there are no changes to the headset, data collector, tablet or cables. The device software was updated to provide the following: • An improved user interface that includes options to add hospital and patient details such as metadata to the signal, options to view the signal in real-time, options to review the signal after completing a recording, and automatic stopping of recording based on specified time and heartbeat intervals. • Calculate and display statistics from the signal that are helpful for signal evaluation.
Testing Summary:	Design Verification and Validation was performed in accordance with approved internal design controls procedures, and in accordance with 21 CFR 820.30. Risk analysis was conducted to review the updated software and to confirm that all software-based risk controls were implemented and verified. An overall system verification was also performed to ensure that the system operates as per design inputs. Software validation was performed with a Level of Concern determined to be moderate, or level B (the same level as the software that was reviewed in DEN140040). The device met all acceptance criteria during verification and validation tests and demonstrated compliance to design inputs.
Biocompatibility Summary	The changes in this submission were limited to software and therefore, no additional biocompatibility was deemed necessary. Jan Medical submitted the evaluation of biocompatibility of the BrainPulse 1100 device components for direct and indirect patient contact and for biocompatibility in compliance to *ISO 10993 Part 1 Biological Evaluation of Medical Devices* as part of DEN140040.