March 7, 2019

Innovative Neurological Devices LLC
Bart Waclawik
President
13295 Illinois Street, Suite 312
Carmel, Indiana 46032

Re: K182311
Trade/Device Name: Cervella
Regulation Number: 21 CFR 882.5800
Regulation Name: Cranial Electrotherapy Stimulator
Regulatory Class: Class III
Product Code: JXK
Dated: February 1, 2019
Received: February 4, 2019

Dear Bart Waclawik:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Pamela D. Scott -S

Digitally signed by Pamela D. Scott -S
Date: 2019.03.07 22:01:53 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183211

Device Name
Cervella

Indications for Use *(Describe)*
Cervella Cranial Electrotherapy Stimulator (CES) is indicated for treatment of insomnia, depression, or anxiety.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR § 807.92(c), 510(k) summary is provided.

I. DATE PREPARED: March 5, 2019

II. SUBMITTER

INNOVATIVE NEUROLOGICAL DEVICES LLC
13295 Illinois St, Suite 312
Carmel, IN 46032
Phone: (855) 413-3300
Contact Person: Bart Waclawik

III. OFFICIAL CORRESPONDENCE/CONTACT PERSON

Bart Waclawik
President | CEO
INNOVATIVE NEUROLOGICAL DEVICES LLC
Phone: (855) 413-3300
e-mail: regulatory@cervella.us

IV. DEVICE

Brand Name of Device:	Cervella™
Common or Usual Name:	Cranial Electrotherapy Stimulator (CES)
Classification Name:	Stimulator, Cranial, Electrotherapy, a preamendment Class III device per 21 CFR §882.5800
Regulatory Class:	III
Product Code:	JXK

V. PREDICATE DEVICES

Device Trade Name:	CES Ultra™
Device Company:	Neuro-Fitness, LLC
510(k) Numbers:	K062284

Device Trade Name:	Alpha-Stim CS
Device Company:	Electromedical Products Inc.
510(k) Numbers:	K903014

VI. DEVICE DESCRIPTION

Cervella Cranial Electrotherapy Stimulator (CES) is a device that delivers small pulses of electrical current through patient's brain. The stimulator is powered by an internal rechargeable battery which provides a low-level constant current to the cranium via a pair of conductive electrodes placed bilaterally on the mastoid process. The electrodes are incorporated into earpads of stereo over-ear noise-cancelling headphones. The patient can use the audio (through a separate dedicated Bluetooth connection) and noise cancelling features of the stereo headphones during treatment (e.g. music listening). The stimulator is controlled via a software application (app) installed on the patient's smart device (e.g. smartphone). The app communicates with the device through a dedicated Bluetooth® LE connection that is independent of the optional Bluetooth connection for audio listening purposes. The patient uses the app to adjust the intensity level, frequency, and duration of the treatment. The app also allows the patient to automatically store the treatment history for review by the patient's healthcare provider.

VII. INDICATIONS FOR USE

Cervella is indicated for the treatment of insomnia, depression, or anxiety.

VIII. SUBSTANTIAL EQUIVALENCE

The Cervella CES is substantially equivalent with respect to indications for use, stimulation parameters (i.e. current levels, frequencies, pulse width and amplitude), and electrode placement to predicate devices CES Ultra cleared by K062284 and Alpha-Stim CS cleared by K903014.

IX. PERFORMANCE DATA DEMONSTRATING SUBSTANTIAL EQUIVALENCE

The Cervella device has the same intended use and operating principles, with similar design features, and functional and performance characteristics as the previously-cleared devices. Cervella is designed to comply with relevant federal and international safety and performance standards.

Cervella has undergone standard engineering bench testing to confirm conformance to design specifications as well as independent laboratory testing to insure conformance with applicable mandatory and voluntary medical device safety standards as follows:

- ES60601-1:2005/(R)2012 and A1:2012
- IEC 60601-1-2 Edition 4.0 2014-02
- IEC 60601-2-10 Edition 2.1 2016-04
- IEC 62133 Edition 2.0 2012-1.

Conformance to mandatory and voluntary standards, combined with no changes in the Indications for Use and no change in the fundamental scientific technology demonstrates substantial equivalence to the predicate devices.

X. SUMMARY OF SIMILARITIES AND DIFFERENCES

Property	Cervella	CES Ultra	Alpha-Stim CS	Differences and Comments
Indications for Use	Cervella is indicated for the treatment of insomnia, depression, or anxiety.	CES Ultra is indicated for the treatment of insomnia, depression, or anxiety.	Alpha-Stim CS is indicated for the treatment of insomnia, depression, or anxiety.	None
Waveform	Symmetrical Biphasic Square Wave	Symmetrical Biphasic Square Wave	Symmetrical Biphasic Square Wave	None
Current Intensity Range	0μA – 500μA adjustable in 50μA increments	0μA – 1500μA continually adjustable	0μA – 500μA adjustable in 50μA increments	Same range as Alpha-Stim, narrower range than CES Ultra
Pulse Width Range	5ms - 1s	2ms	250ms - 1s	Pulse width varies depending on frequency selection
Number of electrodes	Two	Two	Two	None
Electrode Placement	Head (Mastoid process)	Head (Mastoid process or Earlobes)	Head (Earlobes)	Same placement as CES Ultra
Power Source	Li-Ion Battery (3.7V)	Alkaline Battery (9V)	Alkaline Battery (3V)	Cervella battery is rechargeable

Frequency selections	0.5Hz, 1.5Hz, 100Hz	100Hz	0.5Hz, 1.5Hz, 100Hz	Same frequency selection as Alpha-Stim CS
Treatment Range	10 min – 60 min in 10 min intervals	30 min, 60min, or continuous	10, 20, 60 minutes or continuous	Same min-max range as Alpha-Stim
Unit Controls	Via Bluetooth-enabled smart device featuring Cervella app	Built into the device	Built into the device	Wireless operation
Treatment history logging	Automatic	Not available	Not Available	New feature
Ability for patient to use audio and noise cancelling feature of headset during treatment	Optional via dedicated separate Bluetooth connection	Not available	Not Available	New feature
Dimensions and weight	7cmx7cmx2cm	13.5cmx6.4cmx3.3cm	9.8cmx6.3cmx2cm	Cervella is slightly smaller
Enclosure	Plastic	Plastic	Plastic	None

XI. CONCLUSIONS

Cervella CES is substantially equivalent to the listed predicate device without raising any new issues of safety or effectiveness. The new device has the same intended use and operating principles, with similar features, and functional and performance characteristics as the predicates. The device was designed to comply with relevant federal and international safety and performance standards and has been tested to ensure conformity with all applicable medical device safety standards.

