November 8, 2023

Theranica Bioelectronics ltd
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K232152
Trade/Device Name: NerivioInfinity
Regulation Number: 21 CFR 882.5899
Regulation Name: Trunk And Limb Electrical Stimulator To Treat Headache
Regulatory Class: Class II
Product Code: QGT
Dated: July 19, 2023
Received: July 19, 2023

Dear Janice Hogan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jitendra V. Virani -S

CDR Jitendra Virani
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological

and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*
K232152

Device Name

NerivioInfinity

Indications for Use *(Describe)*

The NerivioInfinity is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.

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

Theranica Bio-Electronics LTD.'s NerivioInfinity

K232152

Submitter

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Date Prepared: July 19, 2023

Trade/Device Name: NerivioInfinity
Common or Usual Name: NerivioInfinity
Regulation Number: 21 CFR 882.5899
Regulation Name: Trunk and limb electrical stimulator to treat headache **Regulatory Class:** Class II
Product Code: QGT

Predicate Device:

Device name: Nerivio
Manufacturer: Theranica Bio-Electronics LTD.
510(k) Number: K223169

Device Description:

The NerivioInfinity is a wearable, battery-powered device that is controlled by a mobile application. The system delivers low energy electrical pulses to the upper arm for 45 minutes per treatment, after which the device turns off automatically.

The device is composed of:

- A pair of UltraStim® electrodes (K130987) covered with hydrogel and removable protective film, embedded in an electrodes pad set. The electrodes pad is disposable and replaceable.
- An electronic circuitry that includes microcontroller with firmware and for wireless connection to Android and iOS mobile platforms, LED indicator, a USB-C charging port, a power button for activating the device and a battery contained in a plastic enclosure.
- An armband that is wrapped over the device to secure the NerivioInfinity position on the user's arm is included.

The device is operated and controlled via mobile application software that is installed and run on the user's personal mobile device, such as a mobile phone or tablet. The device's hardware communicates with the mobile application through Bluetooth protocol. This mobile application software allows the user to control the stimulation intensity from 0 to 100% (representing intensity levels of 0-40mA), to start, pause or stop the stimulation program, and to view device status such as the device's connection state, stimulation duration, battery level, and user notifications.

The user is instructed to adjust the intensity to the strongest stimulation level just below the perceived pain level. Treatments with NerivioInfinity are intended to be self-administered by the user immediately after the onset of migraine headache or aura or every other day for prevention.

Intended Use / Indications for Use:

The NerivioInfinity is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.

Summary of Technological Characteristics:

Both the subject device and the predicate device function as remote electrical neuromodulation (REN) devices that utilize electro-stimulation that relieves migraine headache, and/or reduces the number of migraine days (depends on the treatment regime), using equivalent output parameters. The basic pulse structure is biphasic, with symmetrical interleaving phases and rectangular shape. The amplitude shift signal alternates between a nominal maximum and a nominal minimum of the amplitude signal. The maximal output current is 40mA. The assumed impedance is 1K ohm +/- 500 ohms.

Table 1 provides a comparison between the key functional features of the NerivioInfinity and predicate device.

Table 1. Comparison between subject and predicate devices

Characteristic	Subject Device	Predicate Device	Comparison
Submission Number	K232152	K223169	
Device Name	NerivioInfinity	Nerivio	Modified
Manufacturer	Theranica Bio-Electronics LTD.	Theranica Bio-Electronics LTD.	Same
Indications for Use	NerivioInfinity is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12	Nerivio is indicated for acute and/or preventive treatment of migraine with or without aura in patients 12 years of	Same

Characteristic	Subject Device	Predicate Device	Comparison
	years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.	age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment.	
Prescription or OTC	Prescription	Prescription	Same
Electrical waveform	Biphasic rectangular, modulated	Biphasic rectangular, modulated	Same
Electrical output			
Max output voltage **500 Ω** **2 KΩ** **10 KΩ**	 20V (measured) 60V (measured) 60V (measured)	 20V (measured) 60V (measured) 60V (measured)	Same
Max output current **500 Ω** **2 KΩ** **10 KΩ**	 40 mA 30 mA 6mA	 40 mA 30 mA 6mA	Same
Maximum phase charge (500Ω)	8µC	8µC	Same
Maximum average current (500Ω)	1.76mA	1.76mA	Same
Maximum current density (peak) (500Ω)	1.6mA/cm2	1.6mA/cm2	Same
Maximum current density (r.m.s) (500Ω)	0.34mA/cm	0.34mA/cm	Same
Maximum average current density (abs value) (500Ω)	0.07mA/cm2	0.07mA/cm2	Same

Characteristic	Subject Device	Predicate Device	Comparison
Maximum average power density (500Ω) **Frequency**	1.41mW/cm2	1.41mW/cm2	Same
Primary phase duration [µSec]	200	200	Same
Pulse Duration [µSec]	400	400	Same
Electrode Area	25 cm^2	25 cm^2	Same
Treatment location	Upper arm	Upper arm	Same
Treatment duration	45 min.	45 min.	Same
Reusable	Yes	Yes	Same
# of treatments per one device	Up to 18 treatments for each disposable electrodes pad. No limitation for device body unit	18 treatments per one entire device.	Different: The subject device uses disposable electrode pads, and thus the device body unit is reusable beyond 18 treatments. The predicate device is limited to 18 uses.
Power source	Li-Ion cell battery - rechargeable	LiMnO2 cell battery – non-rechargeable	Different: Subject device includes a rechargeable battery.
On/off button	Power push-button	Power push-button	Same
Dimensions	Device – 7.9x3.5x1.7cm	Device (electrodes included)– 12.0x7.5x1.5 cm	Similar

Characteristic	Subject Device	Predicate Device	Comparison
	Electrodes pad – 13.7x7.6x5.3cm Armband – 48.0x10.0x0.3 cm	Armband – 48.0x10.0x0.3 cm	
Weight	Device – 38 gr Electrode pad set – 15 gr Armband – 33 gr	Device (including an embedded pair of electrodes) - 50 gr Armband – 33 gr	Similar
Mobile Application software	Yes	Yes	Similar
Biocompatibility	Yes	Yes	Same
Sterile	No	No	Same
Processor control	Yes	Yes	Same
Wireless control	Yes	Yes	Same
Automatic overload trip	Yes	Yes	Same
Automatic no load trip	Yes	Yes	Same
Automatic shut off	Yes	Yes	Same
Mobile Application treatment control	Yes	Yes	Same
Remote (over-the-air) FW update option	Yes	No	Different

Performance Data:

Non-Clinical Tests:

The NerivioInfinity's design concept and performance is similar to that of the predicate device. The subject device presents a few minor upgrades and additions in the software and firmware, including additions of a rechargeable battery, disposable electrodes, and FOTA upgrade capability. Accordingly, a comprehensive non-clinical bench tests addressed verification and validation of the software, firmware, battery, biocompatibility, usability and device performance were performed.

The company conducted internal bench tests and external lab testing to verify and validate the device battery's safety, firmware verification testing, system performance and labeling verification testing, mobile application software testing. In all instances, the NerivioInfinity functioned as intended and expected. Human factor (Usability) tests were performed to validate that all critical tasks related to

use-errors and knowledge errors were successfully performed by representative intended users and/or mitigated to comply with requirements of usability standards.

Clinical Tests:

No clinical trials were performed with the subject device, given that the therapeutic elements (electrodes, electrical waveform, location on the body, treatment instructions, treatment duration, etc.) are the same as in the predicate device.

Conclusions

The NerivioInfinity has the same intended use and indications for use and substantially similar technological characteristics as its predicate device. The modifications to the device and minor changes to the procedures for use related to the rechargeable battery do not raise different questions of safety or effectiveness. Performance data demonstrate that the NerivioInfinity is as safe and effective as the predicate device. Thus, the NerivioInfinity is substantially equivalent to its predicate device.