November 28, 2017

CEFALY Technology
Jean-Yves Mignolet
R&D Manager
Rue Louis Plescia, 34
Seraing, BE 4102 Liege

Re: K173006
Trade/Device Name: Cefaly® Dual
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache
Regulatory Class: Class II
Product Code: PCC
Dated: September 25, 2017
Received: September 27, 2017

Dear Jean-Yves Mignolet:

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.

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.

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,

William J. Heetderks -S
2017.11.28 12:38:40 -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)*
K173006

Device Name
Cefaly® Dual

Indications for Use *(Describe)*
The Cefaly® Dual is indicated for:
- The acute treatment of migraine with or without aura in patients 18 years of age or older.
- The prophylactic treatment of episodic migraine in patients 18 years of age or older.

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.

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Section 5 510(k) Summary

5.1. Submitter information

Submitter Name: CEFALY Technology
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BELGIUM
Phone: + 32 4 367 67 22
Fax: + 32 4 367 67 02
Contact Person: Jean-Yves MIGNOLET (R&D Manager)
This summary was prepared on: September 25, 2017

5.2. Device information

Device Trade or Proprietary Name: Cefaly® Dual
Device Common or Usual Name (Regulation Description): Transcutaneous electrical nerve stimulator to treat headache
Device Classification Name: Stimulator, Nerve, Electrical, Transcutaneous, For Migraine (21 CRF 882.5891, Product Code PCC)
Device Class: Class II

5.3. Substantial equivalency

Substantial Equivalency is claimed against the following legally marketed devices:

- Cefaly® Acute (510(k) number K171446)
- Cefaly® (510(k) number K160237)

In particular, while the Cefaly® Acute has one stimulation program indicated for the acute treatment of migraine with or without aura and the Cefaly® has one stimulation program indicated for the prophylactic treatment of episodic migraine, the Cefaly® Dual device combines the output modes (stimulation programs) of the two predicate devices. Consequently, the Cefaly® Dual combines the indications for use of the two predicate devices (see Section 5.5).

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5.4. Description of the device

The Cefaly® Dual device is a supraorbital transcutaneous electrical nerve stimulator device to be applied on the forehead. A self-adhesive electrode with 2 conductive zones is placed on the forehead. This double electrode is directly connected to the device.

The Cefaly® Dual is operated by a rechargeable battery. A pressure on the single button allows selecting and starting a stimulation program, which runs automatically.

The electrical impulses generated by the Cefaly® Dual device are transmitted transcutaneously via the supraorbital electrode to excite (trigger action potentials on) the supratrochlearis and supraorbitalis nerves. Supratrochlearis and supraorbitalis (or supratrochlear and supraorbital) nerves belong to the upper branch of the trigeminal nerve (V1). Therefore, the supraorbital neurostimulation is also known as external trigeminal nerve stimulation. The supraorbital neurostimulation generates an analgesic effect and is intended to treat migraine headaches.

5.5. Indications for use of the device

The indications for use of the Cefaly® Dual are:

- The acute treatment of migraine with or without aura in patients 18 years of age or older;
- The prophylactic treatment of episodic migraine in patients 18 years of age or older.

5.6. Summary of the technological characteristics of the Cefaly® Dual in comparison with the predicate Cefaly® Acute and Cefaly® devices

The Cefaly® Dual device is significantly equivalent to the legally marketed devices Cefaly® Acute (K171446) and Cefaly® (K160237) in terms of technological characteristics (design, material, energy source), except for the button color, and it combines the output modes of the two predicate devices. In particular, while each predicate device offers a single stimulation program for given indications for use, the Cefaly® Dual offers these two different stimulation programs in a single device, and each stimulation program is associated with its specific FDA-approved indications for use.

The Cefaly® Dual device is made of a plastic casing identical to that of the predicate Cefaly® Acute and Cefaly® devices. Only the button color is changed to easily differentiate the three devices. It works with the same electrode as the predicate devices. It is powered by the same battery. The electronics inside the device is also the same: only the software has been adapted. The Cefaly® Dual device delivers biphasic impulses of the same pulse shape and width (250 µs)

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than the predicate devices. The repetition frequency of the impulses of the Cefaly® Dual device depends on the selected stimulation program. For the program indicated for the acute treatment of migraine (Program 1), the frequency is 100 Hz, as for the Cefaly® Acute. For the program indicated for the prophylactic treatment of episodic migraine (Program 2), the frequency is 60 Hz, as for the Cefaly®.

	Cefaly® Acute	**Cefaly®**	**Cefaly® Dual**
510 (k) Number	K171446	K160237	K173006
Manufacturer	CEFALY Technology	CEFALY Technology	CEFALY Technology
Weight	12 g	12 g	12 g
Dimensions	55 mm x 40 mm x 15 mm	55 mm x 40 mm x 15 mm	55 mm x 40 mm x 15 mm
Housing materials	Plastic PC	Plastic PC	Plastic PC
Electrodes	Cefaly® electrode	Cefaly® electrode	Cefaly® electrode
Power Source	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery
Software provided	1 fixed program for the acute treatment of migraine attacks (Program 1)	1 fixed program for the prophylactic treatment of migraine (Program 2)	2 fixed programs: - 1 fixed program for the acute treatment of migraine attacks (Program 1) - 1 fixed program for prophylactic treatment of migraine (Program 2)
Program 1: Max. output current Pulse width Pulse frequency Session duration	 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	Not included	 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes
Program 2: Max. output current Pulse width Pulse frequency Session duration	Not included	 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes
Waveform	Biphasic	Biphasic	Biphasic
Shape	Rectangular Full compensated Symmetrical	Rectangular Full compensated Symmetrical	Rectangular Full compensated Symmetrical
Net charge (µC) per pulse	0	0	0
Maximum output current (mA): At 500 ohms At 2,000 ohms At 10,000 ohms	 16 16 6	 16 16 6	 16 16 6
Maximum current density (mA/cm2, r.m.s) at 500 ohms	2.37	2.37	2.37

TVA: BE 870.578.661
Banque ING: 340-0330872-43
IBAN: BE66 3400 3308 7243
BIC: BBRUBEBB

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Maximum average power density (W/cm2, r.m.s) at 500 ohms	0.000047	0.000017	0.000047

5.7. Non-Clinical Performance Testing

The Cefaly® Dual device is compliant to the same international standards as the legally marketed Cefaly® Acute device (K171446) and Cefaly® device (K160237).

Standards	Cefaly® Acute	Cefaly®	Cefaly® Dual
IEC 60601-1	Yes	Yes	Yes
IEC 60601-1-2	Yes	Yes	Yes
IEC 60601-1-6	Yes	Yes	Yes
IEC 60601-1-11	Yes	Yes	Yes
IEC 60601-2-10	Yes	Yes	Yes
IEC 62366	Yes	Yes	Yes

5.8. Conclusion

The subject device is significantly equivalent to the legally marketed predicate Cefaly® Acute and Cefaly® devices.

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