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9/29/2020

CEFALY Technology
% Parul Chansoria
CEO & Founder, Regulatory Consultant
Elexes Medical Consulting
6494 Tralee Village Dr
Dublin, California 94568

Re: K201895
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: July 2, 2020
Received: July 8, 2020

Dear Parul Chansoria:

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/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 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 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,

Xiaorui Tang, Ph.D.
Interim 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)*
K201895

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.

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5.1 SUBMITTER

CEFALY Technology,
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Contact Person:
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Summary Prepared: June 25, 2020

5.2 DEVICE

Common/Usual name/Regulation Description: Transcutaneous electrical nerve stimulator to treat headache
Trade Name: Cefaly® Dual
Classification Name: Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulatory Class: Class II
Classification Panel: Neurology
Product Code: PCC
Regulation Number: 21 CFR 882.5891

5.3 PREDICATE DEVICE

Cefaly® Dual is substantially equivalent to the following cleared device:

Company	Product	510(k) Number
CEFALY Technology	**Cefaly® Dual**	K173006

5.4 DEVICE DESCRIPTION

The Cefaly® Dual device indicated for an OTC (also referred to as the Subject Device) is a supraorbital transcutaneous electrical nerve stimulator device to be applied on the forehead. A

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self-adhesive electrode with 2 conductive zones is placed on the forehead. This double electrode is directly connected to the device.

The Subject Device is operated by a rechargeable battery. Pressure on the single button allows selecting and starting a stimulation program, which runs automatically.

The electrical impulses generated by the Subject 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

The indications for use of the Cefaly® Dual for an **over-the-counter** use 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 TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject Device is identical to the legally marketed Predicate Cefaly® Dual (K173006) in terms of technological characteristics (design, material, and energy source).

The Subject Device is made of a plastic casing identical to that of the Predicate. It works with the same electrode as the Predicate Device. It is powered by the same battery. The electronics inside the device are also the same. The Subject Device delivers biphasic impulses of the same pulse shape and width (250 µs) as the Predicate Device. The repetition frequency of the impulses of the Subject Device depends on the selected stimulation program. The frequencies delivered by the Subject Device for the treatment of Migraine is the same as that of the Predicate.

Table 1: An overview of the Subject Device w.r.t. thePredicate Device

Parameter	**Subject Device Cefaly® Dual (indicated for OTC)**	**Predicate Cefaly® Dual (indicated for Rx)**	**Equivalence**
Manufacturer	CEFALY Technology	CEFALY Technology	-
Device Name	**Cefaly® Dual**	**Cefaly® Dual**	**-**

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510(k) number	-	K173006	-
Product Code	PCC	PCC	Equivalent
Regulation Number	882.5891	882.5891	Equivalent
Regulatory Class	II	II	Equivalent
Indications for use	The indications for use of the Cefaly® Dual for an **over-the-counter** use 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.	The indications for use of the Cefaly® Dual for an **Rx** use 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.	Different While the clinical application, the intended users and use remains identical, the difference is only in terms of labelling change where the Subject Device is to be indicated for an OTC use instead of Rx.
Power Source	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	Equivalent
Channels	1	1	Equivalent
Software provided	2 fixed programs: - 1 fixed program for the acute treatment of migraine attacks (Program 1) - 1 fixed program for	2 fixed programs: - 1 fixed program for the acute treatment of migraine attacks (Program 1) - 1 fixed program for	Equivalent

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	prophylactic treatment of migraine (Program 2)	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	16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	Equivalent
Program 2: Max. output current Pulse width Pulse frequency Session duration	16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	Equivalent
Waveform	Biphasic	Biphasic	Equivalent
Shape	Rectangular Full compensated Symmetrical	Rectangular Full compensated Symmetrical	Equivalent
Net charge (µC) per pulse	0	0	Equivalent
Maximum output current (mA): At 500 ohms At 2,000 ohms At 10,000 ohms	 16 16 6	 16 16 6	Equivalent
Maximum current density (mA/cm2, r.m.s) at 500 ohms	2.37	2.37	Equivalent
Maximum average power density (W/cm2,	0.000047	0.000047	Equivalent

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r.m.s) at 500 ohms			

Differences

While the clinical application, the intended users and use remains identical, the difference is only in terms of labelling change where the Subject Device is to be indicated for an OTC use instead of Rx.

5.7 NON-CLINICAL STUDY

The Subject Device is compliant to the same international standards as the legally marketed Predicate (K173006). To support the change in the indications for use from an Rx to an OTC use, a Human Factors validation study was conducted with the Cefaly® Dual (Subject Device).

5.8 SOFTWARE

The Subject Device software is identical to the software used in the Predicate Device.

5.9 CLINICAL STUDY

Not Applicable. Clinical performance testing was not performed with the Subject Device to support equivalence, as there are no differences between the Subject Device and the Predicate Device.

5.10 CONCLUSION

The Subject Device is substantially equivalent to the Predicate Device in terms of technological characteristics, system operating ranges, and intended use. The Subject Device is as safe and effective as the Predicate Device (K173006).