DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 4, 2016

CEFALY Technologies
Jean-Yves Mignolet
R&D Manager
ZI des Hauts Sarts
4eme Avenue 5
Herstal, Liege, 4040 Belgium

Re: K160237
Trade/Device Name: CEFALY®
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous electrical nerve stimulator to treat headache
Regulatory Class: Class II
Product Code: PCC
Dated: January 29, 2016
Received: February 1, 2016

Dear Mr. 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.

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" (21CFR 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 yours,

Michael J. Hoffmann -A

for Carlos L. Peña, Ph.D., M.S.
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)*
K160237

Device Name
Cefaly®

Indications for Use *(Describe)*
The Cefaly® device is indicated for 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 6 510(k) Summary

Submitter Name: CEFALY Technology
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Contact Person: Jean-Yves MIGNOLET (R&D Manager)
This summary was prepared on: January 2016

Device Trade or Proprietary Name: Cefaly®
Device Common or usual name: Supraorbital transcutaneous nerve stimulator
Device Classification Name: Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Classification Product Code: PCC

Substantial Equivalency is claimed against the following legally marketed device: Cefaly®. The De Novo Number is DEN120019 and the 510(k) Number is K122566.

Description of the device:
Cefaly® device is a supraorbital transcutaneous 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.
Cefaly® is operated by a rechargeable battery. A pressure on the single switch starts a program, which runs automatically for 20 minutes.
The electrical impulses generated by the Cefaly® device are transmitted transcutaneously via the supraorbital electrode to excite (trigger action potentials) 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 a sedative effect and is intended to treat migraine headaches.

CEFALY®
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Intended use of the device:
The Cefaly® device is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

Comparison between the original and the modified, improved version of the Cefaly®:
The intended use and the scientific technology of the modified Cefaly® device are identical to those of the original version of the Cefaly® device. The modified version of the Cefaly® has exactly the same output stimulation parameters than the legally marketed Cefaly®. The device modifications concern the power supply, the dimensional specifications, and the fixing system between the device and the electrode. The risk analysis did not show any unacceptable risk resulting from these device modifications (see Section 15). The modified version of the Cefaly® is therefore as safe and as effective than the legally marketed Cefaly®.

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