



Food and Drug Administration  
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Silver Spring, MD 20993-0002

September 15, 2017

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

Re: K171446

Trade/Device Name: Cefaly® Acute  
Regulation Number: 21 CFR 882.5891  
Regulation Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache  
Regulatory Class: Class II  
Product Code: PCC  
Dated: May 16, 2017  
Received: August 14, 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.

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

William J. Heetderks -S  
2017.09.15 16:45:15 -04'00'

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

## Indications for Use

510(k) Number (if known)

K171446

Device Name

Cefaly® Acute

Indications for Use (Describe)

Cefaly® Acute is indicated for the acute treatment of migraine with or without aura 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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## Section 5

## 510(k) Summary

### 5.1. Submitter information

**Submitter Name:** CEFALY Technology

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B-4102 SERAING  
BELGIUM

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**Contact Person:** Jean-Yves MIGNOLET (R&D Manager)

**This summary was prepared on:** May 5, 2017

### 5.2. Device information

**Device Trade or Proprietary Name:** Cefaly® Acute

**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 device: Cefaly® (510(k) number K160237).

### 5.4. Description of the device

The Cefaly® Acute 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® Acute is operated by a rechargeable battery. A pressure on the single switch starts a program, which runs automatically for 60 minutes.

The electrical impulses generated by the Cefaly® Acute 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 acute migraine headaches.

### 5.5. Indications for use of the device

The Cefaly® Acute is indicated for the acute treatment of migraine with or without aura in patients 18 years of age or older.

### 5.6. Summary of the technological characteristics of the Cefaly® Acute in comparison with the predicate Cefaly®

The Cefaly® Acute device is significantly equivalent to the legally marketed device Cefaly® (K160237), in terms of shape and technology, except for two of the output parameters (frequency of the pulses and duration of a session) and for the button color.

The Cefaly® Acute device is made of a plastic casing identical to that of the predicate Cefaly®. Only the button color is changed to easily differentiate the two devices. It works with the same electrode as the predicate device. It is powered by the same battery. The electronics inside the device is also the same: only the software has been adapted. The Cefaly® Acute device delivers biphasic impulses of the same pulse shape and width (250µs) than the predicate device. The repetition frequency of the impulses in the Cefaly® Acute is 100Hz, while in the predicate Cefaly® it is 60Hz. A session for the Cefaly® Acute lasts 60 minutes, while for the predicate Cefaly® it lasts 20 minutes.

#### 5.6.1. Basic characteristics

|                    | <b>Cefaly®</b>                    | <b>Cefaly® Acute</b>              |
|--------------------|-----------------------------------|-----------------------------------|
| 510 (k) Number     | K160237                           | K171446                           |
| Device Name        | Cefaly®                           | Cefaly® Acute                     |
| Manufacturer       | CEFALY Technology                 | CEFALY Technology                 |
| Power Source       | 1 rechargeable LiPo 3.7 V battery | 1 rechargeable LiPo 3.7 V battery |
| Channels           | 1                                 | 1                                 |
| Computerized       | Yes                               | Yes                               |
| Software provided  | 1 fixed program                   | 1 fixed program                   |
| Constant current   | Yes                               | Yes                               |
| Constant voltage   | No                                | No                                |
| Max output current | 16 mA                             | 16 mA                             |

|                                       |                         |                         |
|---------------------------------------|-------------------------|-------------------------|
| Max output voltage (2kOhms)           | 32 Volts                | 32 Volts                |
| Automatic overload trip voltage level | Yes                     | Yes                     |
| Automatic no load trip                | No                      | No                      |
| Patient override control method       | On/Off button           | On/Off button           |
| Max leakage current                   | None (battery operated) | None (battery operated) |
| Electrodes                            | Cefaly® electrode       | Cefaly® electrode       |
| Indicator display: Unit functioning   | Yes                     | Yes                     |
| Low battery indicator                 | Yes                     | Yes                     |
| Set-up mAmp                           | Yes                     | Yes                     |
| Set-up parameters                     | No                      | No                      |
| Standards:                            |                         |                         |
| IEC 60601-1                           | Yes                     | Yes                     |
| IEC 60601-1-2                         | Yes                     | Yes                     |
| IEC 60601-1-6                         | Yes                     | Yes                     |
| IEC 60601-1-11                        | Yes                     | Yes                     |
| IEC 60601-2-10                        | Yes                     | Yes                     |
| IEC 62366                             | Yes                     | Yes                     |
| Timer setting                         | Yes                     | Yes                     |
| Weight                                | 12 g                    | 12 g                    |
| Dimensions                            | 55 mm x 40 mm x 15 mm   | 55 mm x 40 mm x 15 mm   |
| Housing materials                     | Plastic PC              | Plastic PC              |

Basic characteristics of the Cefaly® device and the Cefaly® Acute device are exactly the same.

### 5.6.2. Output mode

|                                                                               | <b>Cefaly®</b>                                                            | <b>Cefaly® Acute</b>                                                      |
|-------------------------------------------------------------------------------|---------------------------------------------------------------------------|---------------------------------------------------------------------------|
| Waveform                                                                      | Biphasic                                                                  | Biphasic                                                                  |
| Shape                                                                         | Rectangular                                                               | Rectangular                                                               |
|                                                                               | Full compensated                                                          | Full compensated                                                          |
|                                                                               | Symmetrical                                                               | Symmetrical                                                               |
| Net charge (µC) per pulse                                                     | 0                                                                         | 0                                                                         |
| Method                                                                        | Same charge quantity on positive and negative impulse                     | Same charge quantity on positive and negative impulse                     |
| Max phase amplitude                                                           | 16 mA with a load of a 4.7 µF capacitor parallel with 2.2Kohms resistance | 16 mA with a load of a 4.7 µF capacitor parallel with 2.2Kohms resistance |
| Maximum output voltage (V):<br>At 500 ohms<br>At 2,000 ohms<br>At 10,000 ohms | <br>8<br>32<br>60                                                         | <br>8<br>32<br>60                                                         |
| Maximum output current (mA):                                                  |                                                                           |                                                                           |

|                                                                   |                                   |                                   |
|-------------------------------------------------------------------|-----------------------------------|-----------------------------------|
| At 500 ohms                                                       | 16                                | 16                                |
| At 2,000 ohms                                                     | 16                                | 16                                |
| At 10,000 ohms                                                    | 6                                 | 6                                 |
| Duration of the primary (depolarizing) phase (µS)                 | 250                               | 250                               |
| Standby duration between the two phases (µS)                      | 5                                 | 5                                 |
| Pulse duration (µS)                                               | 505                               | 505                               |
| Maximum current density (mA/cm <sup>2</sup> , r.m.s.) at 500 ohms | 2.37                              | 2.37                              |
| Maximum average power density (W/cm <sup>2</sup> ) at 500 ohms    | 0.000017                          | 0.000047                          |
| Maximum average current (average absolute value, mA) at 500 ohms  | 0.48                              | 0.8                               |
| Phase rise time                                                   | 2 µS                              | 2 µS                              |
| Phase decay time                                                  | 2 µS                              | 2 µS                              |
| Interphase interval                                               | nil                               | nil                               |
| Frequency range                                                   | 60 Hz fixed                       | 100 Hz fixed                      |
| Burst mode                                                        | No                                | No                                |
| Maximum Phase Charge (µC) @ 500 Ohms                              | 4                                 | 4                                 |
| Modulation options                                                |                                   |                                   |
| Amplitude                                                         | 0 - 16 mA                         | 0 - 16 mA                         |
| Frequency                                                         | Fixed @ 60 Hz                     | Fixed @ 100 Hz                    |
| Duration                                                          | Fixed @ 250 µS                    | Fixed @ 250 µS                    |
| Ramp modulations                                                  |                                   |                                   |
| ramp up                                                           | 14 minutes                        | 14 minutes                        |
| ramp down                                                         | 1 minute                          | 1 minute                          |
| Amplitude modulation                                              | Amplitude is adjusted by the user | Amplitude is adjusted by the user |

All output mode features are identical for the Cefaly® and the Cefaly® Acute, except the frequency of the stimulation, which has a direct impact on the maximum average power density and the maximum average current.

### 5.6.3. Materials

|                          | <b>Cefaly®</b> | <b>Cefaly® Acute</b> |
|--------------------------|----------------|----------------------|
| Device housing materials | Plastic PC     | Plastic PC           |

Materials of the Cefaly® device and the Cefaly® Acute device are exactly the same. The Cefaly® Acute device is made of a plastic casing identical to that of the Cefaly® device. Only the button color is changed to easily differentiate the two devices, which has no impact on substantial equivalence.

#### **5.6.4. Principle of operation**

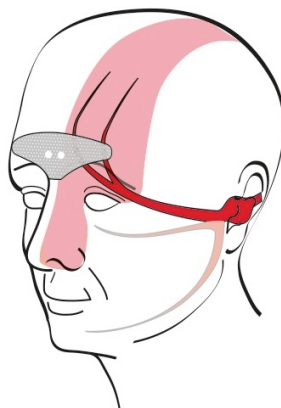
The Cefaly® device and the Cefaly® Acute device are both external cranial neurostimulators designed for supraorbital neurostimulation (also known as external trigeminal nerve stimulation). Trigeminal nerve stimulation induces a neuromodulation of the trigeminal system in order to treat migraine.

The Cefaly® device and the Cefaly® Acute device both generate electrical impulses which are transmitted transcutaneously via a bipolar self-adhesive electrode placed on the forehead.

The Cefaly® device and the Cefaly® Acute device both operate on direct electrical energy which is output from a rechargeable 3.7V LiPo battery.

The Cefaly® device and the Cefaly® Acute device both deliver electrical energy in the form of rectangular biphasic pulses. The intensity is increasing linearly from 1mA to a maximum of 16 mA during 14 minutes, and then stays constant for 6 minutes in the Cefaly® device and for 46 minutes in the Cefaly® Acute device. The pulse frequency is 60 Hz in the Cefaly® device and 100 Hz in the Cefaly® Acute device. The pulse width is 250 µs in both devices.

The Cefaly® Acute device uses the legally marketed electrode cleared with the Cefaly® device (K160237). The supraorbital electrode of the Cefaly® device is designed in order to cover both sides of the supratrochlearis and supraorbitalis nerves, which are branches of the trigeminal nerve (Figure 1).



**Figure 1: The electrode placed on the forehead covers the supratrochlearis and supraorbitalis nerves for both the Cefaly® device and the Cefaly® Acute device.**

The electrical impulses generated by the Cefaly® device and the Cefaly® Acute device are both 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 principle of operation of the Cefaly® device and the Cefaly® Acute device is exactly the same.

## 5.7. Pre-Clinical Testing

The Cefaly® Acute device is compliant to the same international standards that of the legally marketed Cefaly® device (K160237).

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

## 5.8. Clinical Testing

### *Randomized, sham-controlled clinical trial*

**Purpose:** To provide evidence of safety and efficacy of the Cefaly® Acute for the acute treatment of migraine with or without aura in patients 18 years of age or older

**Study population:** 106 patients (93 females and 13 males) having a migraine attack with or without aura

**Adverse events encountered:** One adverse event (nausea) occurred but this event was minor and totally reversible (nausea resolved by itself after 20 minutes). There were no severe adverse events (SAE), nor were any subjective complaints or side effects reported in either group within the 24 hours after the beginning of the treatment

**Results:** In the ITT analysis, the primary outcome was the change of pain score from baseline to one hour of treatment. The pain score was measured on an 11-point visual analog scale (VAS). Based on the ITT population (N=106) with the missing value imputed by the last observation carried forward, the mean change in VAS pain score from baseline to 1 hour was  $-3.46 \pm 2.32$  in Cefaly Acute group and  $-1.78 \pm 1.89$  in sham group. The treatment difference (Cefaly Acute – sham) was  $-1.68$ , which was statistically significant at two-sided 0.05 alpha level. The pain relief was as well observed in the verum group compared to the sham group at 2-hour and 24-hour time

points. Anti-migraine rescue medication intake within the 24 hours after the beginning of the treatment is not significantly lower in the verum group.

## **5.9. Conclusion**

Data from the nonclinical and clinical tests demonstrate that the subject device is significantly equivalent to the legally marketed device identified in paragraph (5.3) of this section.