December 13, 2022

CEFALY Technology
℅ Parul Chansoria
CEO and Founder
Elexes Medical Consulting, LLC
30 N Gould St Ste R
Sheridan, Wyoming 82801

Re: K212071
Trade/Device Name: Cefaly Dual Enhanced with RFID - OTC, Cefaly Dual Enhanced with RFID - Rx, Cefaly Dual Connected - OTC, Cefaly Dual Connected - Rx
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous Electrical Nerve Stimulator To Treat Headache
Regulatory Class: Class II
Product Code: PCC
Dated: January 6, 2022
Received: January 10, 2022

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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS MBA
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)*
K212071

Device Name
Cefaly Dual Series (Cefaly Dual Enhanced with RFID - OTC, Cefaly Dual Enhanced with RFID - Rx, Cefaly Dual Connected - OTC, Cefaly Dual Connected - Rx)

Indications for Use *(Describe)*
Cefaly Dual Connected – OTC and Cefaly Dual Enhanced with RFID – OTC are indicated for:

1. Acute treatment of migraine with or without aura in patients 18 years of age or older
2. Preventative treatment of migraine in patients 18 years of age or older

Cefaly Dual Connected – Rx and Cefaly Dual Enhanced With RFID – Rx are indicated for:

1. Acute treatment of migraine with or without aura in patients 18 years of age or older

2. Prophylactic treatment of 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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CEFALY

5.1. Submitter's information

CEFALY Technology,
LIEGE Science Park, Rue Louis Plescia,
34, 4102 Seraing,
Belgium.

Contact Person

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CEO & Founder, Elexes Medical Consulting
Telephone: + 408-475-8091
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Summary Prepared: December 12, 2022

5.2. Device Information

5.2.1. Common/Usual name: Transcutaneous electrical nerve stimulator to treat headache
Trade Name: Cefaly® Dual Connected OTC
Regulation name: Transcutaneous electrical nerve stimulator to treat headache
Regulation Number: 21 CFR 882.5891
Regulatory Class: Class II
Classification panel: Neurology
Product Code: PCC

5.2.2. Common/Usual name: Transcutaneous electrical nerve stimulator to treat headache
Trade Name: Cefaly® Dual Connected R_x
Regulation name: Transcutaneous electrical nerve stimulator to treat headache
Regulation number: 21 CFR 882.5891
Regulatory Class: Class II
Classification panel: Neurology
Product Code: PCC

5.2.3. Common/Usual name: Transcutaneous electrical nerve stimulator to treat headache
Trade Name: Cefaly® Dual Enhanced with RFID - OTC
Classification name: Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulation number: 21 CFR 882.5891
Regulatory Class: Class II
Classification panel: Neurology
Product Code: PCC

5.2.4. Common/Usual name: Transcutaneous electrical nerve stimulator to treat headache
Trade Name: Cefaly® Dual Enhanced with RFID - R_x
Classification name: Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulation number: 21 CFR 882.5891
Regulatory Class: Class II
Classification panel: Neurology
Product Code: PCC

5.3. Predicate Device Information

The following Predicate Devices are used:

Company	Product	510(k) Number	Subject Device
CEFALY Technology	**Cefaly® Dual**	K173006	• Cefaly® Dual Connected R_x, • Cefaly® Dual Enhanced with RFID R_x
CEFALY Technology	**Cefaly® Dual**	K201895	• Cefaly® Dual Connected OTC, • Cefaly® Dual

			Enhanced with RFID OTC

The Predicate Devices stated above are not subject to recall by the FDA.

5.4. Device Description

Cefaly® Dual Series by CEFALY Technology consists of Cefaly® Dual Enhanced with RFID - R_x, Cefaly® Dual Enhanced with RFID - OTC, Cefaly® Dual Connected - R_x and Cefaly® Dual Connected - OTC. The Cefaly® Dual Series of devices are identical to the Predicate Devices Cefaly® Dual - R_x (K173006) and Cefaly® Dual - OTC (K201895).

The submission includes CEFALY® Dual Enhanced with RFID and CEFALY® Dual Connected which are indicated for R_x, are identical to the Predicate Devices CEFALY® Dual - R_x (K173006) and CEFALY® Dual Enhanced with RFID and CEFALY® Dual Connected, which are indicated for OTC, are identical to the Predicate Devices CEFALY® Dual - OTC (K201895). Additionally, all the devices in the CEFALY® Dual Series are similar in construction and materials and use the same components (electronics and electrical components, and firmware), including the component that comes into patient contact which is the CEFALY® Electrode. The notable differences between the Subject and Predicate devices are Bluetooth technology and mobile application for the purpose of displaying device data, the new docking station, RFID for electrode detection, audio/visual indicators, and the dimensions and the weight of the electrode.

The Cefaly® Dual Series of devices are small, non-invasive, and portable devices meant to be worn on the forehead using a self-adhesive electrode to treat migraine similar to Cefaly® Dual (K201895 OTC and K173006 R_x).

5.5. Indications for Use

Cefaly Dual Connected – OTC and Cefaly Dual Enhanced with RFID – OTC are indicated for:

1. Acute treatment of migraine with or without aura in patients 18 years of age or older
2. Preventative treatment of migraine in patients 18 years of age or older

Cefaly Dual Connected – Rx and Cefaly Dual Enhanced With RFID – Rx are indicated for:

1. Acute treatment of migraine with or without aura in patients 18 years of age or older
2. Prophylactic treatment of migraine in patients 18 years of age or older

5.6. Technological Characteristics

5.6.1. Comparison of the Technological Characteristics between Subject Device and Predicate Device

Parameters	Subject Device: Cefaly® Dual Connected - OTC	Predicate Device: Cefaly® Dual	Equivalence
Manufacturer	CEFALY Technology	CEFALY Technology	
Device Name	CEFALY® Dual Connected	CEFALY® Dual	-
510(k) Number	-	K201895	-
Product code	PCC	PCC	Equivalent
Regulation No.	21 CFR 882.5891	21 CFR 882.5891	Equivalent
Classification:	II	II	Equivalent
Indications for Use	The indications for use of CEFALY® Dual Connected for an over-the-counter use are:	The indications for CEFALY® Dual for an over-the-counter use are:	Equivalent

	• Acute treatment of migraine with or without aura in patients 18 years of age or older • Preventative treatment of migraine in patients 18 years of age or older	• 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	
Mobile Application	Yes	No	Different
Bluetooth	Yes	No	Different
RFID for electrode detection	Yes	No	Different
Charging System	Charging dock, Power adapter and USB Cable.	Power adapter and USB Cable	Different
Power Source	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	Equivalent

Electrode Metal Plate (RFID tag) Thickness	1 mm	0.4 mm	Different
Weight	25 grams	12 grams	Different
Dimensions	66 mm x 47 mm x 17 mm	55 mm x 40 mm x 15 mm	Different
Channels	1	1	Equivalent
Treatment Programs	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prevent treatment of migraine	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prophylactic treatment of episodic migraine	Equivalent
Waveform	Biphasic	Biphasic	Equivalent
Shape	Rectangular	Rectangular	Equivalent
	Full compensated	Full compensated	Equivalent
	Symmetrical	Symmetrical	Equivalent
Net charge (µC) per pulse	0	0	Equivalent

Maximum output voltage (V): At 500 ohms At 2,000 ohms At 10,000 ohms	 8 32 60	 8 32 60	Equivalent
Maximum output current (mA): At 500 ohms At 2,000 ohms At 10,000 ohms	 16 16 6	 16 16 6	Equivalent
Pulse duration (µs)	505	505	Equivalent
Maximum Phase Charge (µC) @ 500 Ohms	4	4	Equivalent
Type of impedance monitoring system	Electrical	Electrical	Equivalent
Maximum current density (mA/cm^2, r.m.s.) at 500 ohms	2.37	2.37	Equivalent
Treatment Programs output specifications - Program 1			
Amplitude	0 - 16 mA	0 - 16 mA	Equivalent

Pulse width Pulse frequency Session duration	250 µs, fixed 100 Hz, fixed 60 minutes	250 µs, fixed 100 Hz, fixed 60 minutes	
Maximum average current (average absolute value, mA) at 500 ohms	0.8	0.8	Equivalent
Maximum average power density (W/cm^2) at 500 ohms	0.000047	0.000047	Equivalent
Treatment Programs output specifications - Program 2			
Amplitude Pulse width Pulse frequency Session duration	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	Equivalent
Maximum average current (average absolute value, mA) at 500 ohms	0.48	0.48	Equivalent
Maximum average power density (W/cm^2) at 500 ohms	0.000017	0.000017	Equivalent

Audio-visual Indications			
Audio Indicators for low battery, Acute and Prevent Program (Low Battery Charge), Intensity is 10mA, Increase Intensity (For Experienced CEFALY Users), Bluetooth connection and disconnection and electrode detection	Present	Absent	Different
Visual Indicators for low battery, bluetooth connection and disconnection and electrode detection	Present	Absent	Different
Electrode			
Dimensions	94 mm x 20 mm	94 mm x 20 mm	Equivalent
RFID tag	Present	Not Present	Different
Electrode Metal plate	1 mm	0.4 mm	Different

(tinplate) thickness			
Electrode Gel used	Acrylic Hydrogel	Acrylic Hydrogel	Equivalent
Packaging configuration			
Gift Box	Made of cardboard, has a magnetic latch, artwork, and label.	A white box made of cardboard, no magnetic latch and no artwork. The white box slides inside a sleeve that has artwork and label.	Different
Storage Case	The storage case contains a USB cable, charging dock, device, user manual, Instruction guide, and resealable bag consisting of electrodes	The storage case contains a USB, charging adapter, and electrode inside. The device is on a cardboard sheet on top of the storage case. User manual(s) are below the case.	Different
Number of electrodes provided with the device	Three (3)	One (1)	Different

Electrode storage	Resealable bag	Non- resealable bag	Different

5.6.1.1. Similarities between Subject Device and Predicate Device

- The intended use is the same for the Subject and the Predicate Devices and both devices are meant for over-the-counter use.
- Treatment Programs - Waveform characteristics and output specifications are same for both the Subject and Predicate Device.
- The Channels are the same for both the Subject and Predicate Devices.
- Maximum output voltage is the same for both Subject and Predicate Devices.
- Maximum output current is the same for both Subject and Predicate Devices.
- The Power source (Battery) is the same for both Subject and Predicate Devices.
- The Pulse duration, Maximum phase charge and Type of impedance monitoring system is the same for both Subject and Predicate devices.
- The dimensions and patient contacting material used in the electrode is same for both Subject and Predicate devices.

5.6.1.2. Differences between Subject Device and Predicate Device

- The usage of Mobile application and Bluetooth in Subject Device is different from Predicate Device.
- The RFID tag is added to electrode for Subject Device for electrode detection and, electrode metal plate thickness in

Subject Device (1mm) is different from Predicate Device (0.4mm).

- The weight and dimensions of the Subject device is different from Predicate Device.
- The Audio and Visual Indication for low battery, bluetooth and electrode detection in the Subject device is different from Predicate device.
- The charging system in the Subject Device is different in terms of the design and the characteristics of input power. The Charging system of the Subject Device receives DC input from an AC/DC adapter while the charging system in the Predicate Device consists of an AC/DC adapter that receives AC input. However, both charging systems provide identical DC output voltage to the neurostimulator. The safety of the charging system in the Subject Device owing to the differences in design characteristics compared to that in the Predicate Device, is demonstrated by performance testing according to IEC 60601-1.
- The packaging configuration of Subject and Predicate devices are different. However, it does not raise new questions about safety and efficacy.

5.6.2. Comparison of the Technological Characteristics between Subject Device and Predicate Device

Parameters	Subject Device: Cefaly® Dual Connected - R_x	Predicate Device: Cefaly® Dual	Equivalence
Manufacturer	CEFALY Technology	CEFALY Technology	
Device Name	CEFALY® Dual Connected	CEFALY® Dual	-

510(k) Number	-	K173006	-
Product code	PCC	PCC	Equivalent
Regulation No.	21 CFR 882.5891	21 CFR 882.5891	Equivalent
Classification:	II	II	Equivalent
Indications for Use	The indications for use of CEFALY® Dual Connected for an R_x are: ● Acute treatment of migraine with or without aura in patients 18 years of age or older ● Prophylactic treatment of migraine in patients 18 years of age or older	The indications for CEFALY® Dual for an R_x 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	Equivalent
Mobile Application	Yes	No	Different
Bluetooth	Yes	No	Different
RFID for electrode detection	Yes	No	Different

Charging System	Charging dock, Power adapter and USB Cable.	Power adapter and USB Cable	Different
Power Source	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	Equivalent
Electrode metal plate (RFID tag) thickness	1 mm	0.4 mm	Different
Weight	25 grams	12 grams	Different
Dimensions	66 mm x 47 mm x 17 mm	55 mm x 40 mm x 15 mm	Different
Channels	1	1	Equivalent
Treatment Programs	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prevent treatment of migraine	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prophylactic treatment of episodic migraine	Equivalent
Waveform	Biphasic	Biphasic	Equivalent
Shape	Rectangular	Rectangular	Equivalent

	Full compensated	Full compensated	Equivalent
	Symmetrical	Symmetrical	Equivalent
Net charge (µC) per pulse	0	0	Equivalent
Maximum output voltage (V): At 500 ohms At 2,000 ohms At 10,000 ohms	 8 32 60	 8 32 60	Equivalent
Maximum output current (mA): At 500 ohms At 2,000 ohms At 10,000 ohms	 16 16 6	 16 16 6	Equivalent
Pulse duration (µs)	505	505	Equivalent
Maximum Phase Charge (µC) @ 500 Ohms	4	4	Equivalent
Type of impedance monitoring system	Electrical	Electrical	Equivalent

Maximum current density (mA/cm^2, r.m.s.) at 500 ohms	2.37	2.37	Equivalent
Treatment Programs output specifications - Program 1			
Amplitude Pulse width Pulse frequency Session duration	0 - 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	0 - 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	Equivalent
Maximum average current (average absolute value, mA) at 500 ohms	0.8	0.8	Equivalent
Maximum average power density (W/cm^2) at 500 ohms	0.000047	0.000047	Equivalent
Treatment Programs output specifications - Program 2			
Amplitude Pulse width Pulse frequency Session duration	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	Equivalent
Maximum average current (average absolute	0.48	0.48	Equivalent

value, mA) at 500 ohms			
Maximum average power density (W/cm^2) at 500 ohms	0.000017	0.000017	Equivalent
Audio-visual Indications			
Audio Indicators for low battery, Acute and Prevent Program (Low Battery Charge), Intensity is 10mA, Increase Intensity (For Experienced CEFALY Users), Bluetooth connection and disconnection and electrode detection	Present	Absent	Different
Visual Indicators for low battery, bluetooth connection and disconnection and electrode detection	Present	Absent	Different
Electrode			
Dimensions	94 mm x 20 mm	94 mm x 20 mm	Equivalent

RFID tag	Present	Not Present	Different
Electrode Metal plate (tinplate) thickness	1 mm	0.4 mm	Different
Electrode Gel used	Acrylic Hydrogel	Acrylic Hydrogel	Equivalent
Packaging Configuration			
Gift Box	Made of cardboard, has a magnetic latch, artwork, and label.	A white box made of cardboard, no magnetic latch and no artwork. The white box slides inside a sleeve that has artwork and label.	Different
Storage Case	The storage case contains a USB cable, charging dock, device, user manual, Instruction guide, and resealable bag consisting of electrodes	The storage case contains a USB, charging adapter, and electrode inside. The device is on a cardboard sheet on top of the storage case. User manual(s) are below the case.	Different
Number of electrodes provided with the device	Three (3)	One (1)	Different
Electrode storage	Resealable bag	Non- resealable	Different

		bag	

5.6.2.1. Similarities between Subject Device and Predicate Device

- The intended use is the same for the Subject and the Predicate Devices and both devices are meant for Prescription use.
- Treatment Programs - Waveform characteristics and output specifications are same for both the Subject and Predicate Device.
- The Channels are the same for both the Subject and Predicate Devices.
- Maximum output voltage is the same for both Subject and Predicate Devices.
- Maximum output current is the same for both Subject and Predicate Devices.
- The Power source (Battery) is the same for both Subject and Predicate Devices.
- The Pulse duration, Maximum phase charge and Type of impedance monitoring system is the same for both Subject and Predicate devices.
- The dimensions and patient contacting material used in the electrode is same for both Subject and Predicate devices.

5.6.2.2. Differences between Subject Device and Predicate Device

- The usage of Mobile application and Bluetooth in Subject Device is different from Predicate Device.
- The RFID tag is added to electrode for Subject Device for electrode detection and, electrode metal plate thickness in

Subject Device (1mm) is different from Predicate Device (0.4mm).

- The weight and dimensions of the Subject device is different from Predicate Device.
- The Audio and Visual Indication for low battery, bluetooth and electrode detection in the Subject device is different from Predicate device.
- The charging system in the Subject Device is different in terms of the design and the characteristics of input power. The Charging system of the Subject Device receives DC input from an AC/DC adapter while the charging system in the Predicate Device consists of an AC/DC adapter that receives AC input. However, both charging systems provide identical DC output voltage to the neurostimulator. The safety of the charging system in the Subject Device owing to the differences in design characteristics compared to that in the Predicate Device, is demonstrated by performance testing according to IEC 60601-1.
- The packaging configuration of Subject and Predicate devices are different. However, it does not raise new questions about safety and efficacy.

5.6.3. Comparison of the Technological Characteristics between Subject Device and Predicate Device

Parameters	Subject Device: Cefaly® Dual Enhanced with RFID - OTC	Predicate Device: Cefaly® Dual	Equivalence
Manufacturer	CEFALY Technology	CEFALY Technology	

Device Name	CEFALY® Dual Enhanced with RFID	CEFALY® Dual	-
510(k) Number	-	K201895	-
Product code	PCC	PCC	Equivalent
Regulation No.	21 CFR 882.5891	21 CFR 882.5891	Equivalent
Classification:	II	II	Equivalent
Indications for Use	The indications for use of CEFALY® Dual Enhanced with RFID for an over-the-counter use are: ● Acute treatment of migraine with or without aura in patients 18 years of age or older ● Preventative treatment of migraine in patients 18 years of age or older	The indications for 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	Equivalent
Mobile Application	No	No	Equivalent
Bluetooth	No	No	Equivalent

RFID for electrode detection	Yes	No	Different
Charging System	Charging dock, Power adapter and USB Cable	Power adapter and USB Cable	Different
Power Source	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	Equivalent
Electrode Metal Plate Thickness	1 mm	0.4 mm	Different
Weight	25 grams	12 grams	Different
Dimensions	66 mm x 47 mm x 17 mm	55 mm x 40 mm x 15 mm	Different
Channels	1	1	Equivalent
Treatment Programs	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prevent treatment of migraine	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prophylactic treatment of episodic migraine	Equivalent

Waveform	Biphasic	Biphasic	Equivalent
Shape	Rectangular	Rectangular	Equivalent
	Full compensated	Full compensated	Equivalent
	Symmetrical	Symmetrical	Equivalent
Net charge (µC) per pulse	0	0	Equivalent
Maximum output voltage (V): At 500 ohms At 2,000 ohms At 10,000 ohms	 8 32 60	 8 32 60	Equivalent
Maximum output current (mA): At 500 ohms At 2,000 ohms At 10,000 ohms	 16 16 6	 16 16 6	Equivalent
Pulse duration (µs)	505	505	Equivalent
Maximum Phase Charge (µC) @ 500 Ohms	4	4	Equivalent

Type of impedance monitoring system	Electrical	Electrical	Equivalent
Maximum current density (mA/cm^2, r.m.s.) at 500 ohms	2.37	2.37	Equivalent
Treatment Programs output specifications - Program 1			
Amplitude Pulse width Pulse frequency Session duration	0 - 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	0 - 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	Equivalent
Maximum average current (average absolute value, mA) at 500 ohms	0.8	0.8	Equivalent
Maximum average power density (W/cm^2) at 500 ohms	0.000047	0.000047	Equivalent
Treatment Programs output specifications - Program 2			

Amplitude Pulse width Pulse frequency Session duration	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	Equivalent
Maximum average current (average absolute value, mA) at 500 ohms	0.48	0.48	Equivalent
Maximum average power density (W/cm^2) at 500 ohms	0.000017	0.000017	Equivalent
Audio-visual Indications			
Audio Indicators for low battery, Acute and Prevent Program (Low Battery Charge), Intensity is 10mA, Increase Intensity (For Experienced CEFALY Users) and	Present	Absent	Different

electrode detection			
Visual Indicators for low battery and electrode detection	Present	Absent	Different
Electrode			
Dimensions	94 mm x 20 mm	94 mm x 20 mm	Equivalent
RFID tag	Present	Not Present	Different
Electrode Metal plate (tinplate) thickness	1 mm	0.4 mm	Different
Electrode Gel used	Acrylic Hydrogel	Acrylic Hydrogel	Equivalent
Packaging Configuration			
Gift Box	Made of cardboard, has a magnetic latch, artwork, and label.	A white box made of cardboard, no magnetic latch and no artwork. The white box slides inside a sleeve that has artwork and label.	Different
Storage Case	The storage case contains a USB cable, charging dock, device, user manual, Instruction guide, and resealable bag consisting of	The storage case contains a USB, charging adapter, and electrode inside. The device is on a	Different

	electrodes	cardboard sheet on top of the storage case. User manual(s) are below the case.	
Number of electrodes provided with the device	Three (3)	One (1)	Different
Electrode storage	Resealable bag	Non- resealable bag	Different

5.6.3.1. Similarities between Subject Device and Predicate Device

- The intended use is the same for the Subject and Predicate Devices and both devices are meant for over-the-counter use.
- Treatment Programs - Waveform characteristics and output specifications are same for both the Subject and Predicate Devices.
- The Channels are the same for both Subject and Predicate Devices.
- Maximum output voltage is the same for both Subject and Predicate Devices.
- Maximum output current is the same for both Subject and Predicate Devices.
- The Power source (Battery) is the same for both Subject and Predicate Devices.

- The Pulse duration, Maximum phase charge and Type of impedance monitoring system is the same for both Subject and Predicate devices.
- The dimensions and patient contacting material used in the electrode is same for both Subject and Predicate devices.

5.6.3.2. Differences between Subject Device and Predicate Device

- The RFID tag is added to electrode for Subject Device for electrode detection and, electrode metal plate thickness in Subject Device (1mm) is different from Predicate Device (0.4mm).
- The weight and dimensions of the Subject device is different from Predicate Device.
- The Audio and Visual Indication for low battery, bluetooth and electrode detection in the Subject device is different from Predicate device.
- The charging system in the Subject Device is different in terms of the design and the characteristics of input power. The Charging system of the Subject Device receives DC input from an AC/DC adapter while the charging system in the Predicate Device consists of an AC/DC adapter that receives AC input. However, both charging systems provide identical DC output voltage to the neurostimulator. The safety of the charging system in the Subject Device owing to the differences in design characteristics compared to that in the Predicate Device, is demonstrated by performance testing according to IEC 60601-1.
- The packaging configuration of Subject and Predicate devices are different. However, it does not raise new questions about safety and efficacy.

5.6.4. Comparison of the Technological Characteristics between Subject Device and Predicate Device

Parameters	Subject Device: Cefaly® Dual Enhanced with RFID - R_x	Predicate Device: Cefaly® Dual	Equivalence
Manufacturer	CEFALY Technology	CEFALY Technology	
Device Name	CEFALY® Dual Enhanced with RFID	CEFALY® Dual	-
510(k) Number	-	K173006	-
Product code	PCC	PCC	Equivalent
Regulation No.	21 CFR 882.5891	21 CFR 882.5891	Equivalent
Classification:	II	II	Equivalent
Indications for Use	The indications for use of CEFALY® Dual Enhanced with RFID for an R_x use are:	The indications for CEFALY® Dual for an R_x 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	Equivalent

	• Acute treatment of migraine with or without aura in patients 18 years of age or older • Prophylactic treatment of migraine in patients 18 years of age or older	in patients 18 years of age or older	
Mobile Application	No	No	Equivalent
Bluetooth	No	No	Equivalent
RFID for electrode detection	Yes	No	Different
Charging System	Charging dock, USB Cable.	Power adapter and USB Cable	Different
Power Source	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	Equivalent
Electrode Metal Plate (RFID tag) Thickness	1 mm	0.4 mm	Different
Weight	25 grams	12 grams	Different

Dimensions	66 mm x 47 mm x 17 mm	55 mm x 40 mm x 15 mm	Different
Channels	1	1	Equivalent
Treatment Programs	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prevent treatment of migraine	2 programs: ● Program 1 - The acute treatment of migraine attacks ● Program 2 - The prophylactic treatment of episodic migraine	Equivalent
Waveform	Biphasic	Biphasic	Equivalent
Shape	Rectangular	Rectangular	Equivalent
	Full compensated	Full compensated	Equivalent
	Symmetrical	Symmetrical	Equivalent
Net charge (µC) per pulse	0	0	Equivalent
Maximum output voltage		8	Equivalent

(V): At 500 ohms At 2,000 ohms At 10,000 ohms	8 32 60	32 60	
Maximum output current (mA): At 500 ohms At 2,000 ohms At 10,000 ohms	 16 16 6	 16 16 6	Equivalent
Pulse duration (µs)	505	505	Equivalent
Maximum Phase Charge (µC) @ 500 Ohms	4	4	Equivalent
Type of impedance monitoring system	Electrical	Electrical	Equivalent
Maximum current density (mA/cm^2, r.m.s.) at 500 ohms	2.37	2.37	Equivalent
Treatment Programs output specifications - Program 1			

Amplitude Pulse width Pulse frequency Session duration	0 - 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	0 - 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	Equivalent
Maximum average current (average absolute value, mA) at 500 ohms	0.8	0.8	Equivalent
Maximum average power density (W/cm^2) at 500 ohms	0.000047	0.000047	Equivalent
Treatment Programs output specifications - Program 2			
Amplitude Pulse width Pulse frequency Session duration	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	0 - 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	Equivalent
Maximum average current (average absolute value, mA) at 500 ohms	0.48	0.48	Equivalent

Maximum average power density (W/cm^2) at 500 ohms	0.000017	0.000017	Equivalent
Audio-visual Indications			
Audio Indicators for low battery, Acute and Prevent Program (Low Battery Charge), Intensity is 10mA, Increase Intensity (For Experienced CEFALY Users) and electrode detection	Present	Absent	Different
Visual Indicators for low battery and electrode detection	Present	Absent	Different
Electrode			
Dimensions	94 mm x 20 mm	94 mm x 20 mm	Equivalent
RFID tag	Present	Not Present	Different
Electrode Metal plate (tinplate) thickness	1 mm	0.4 mm	Different

Electrode Gel used	Acrylic Hydrogel	Acrylic Hydrogel	Equivalent
Packaging Configuration			
Gift Box	Made of cardboard, has a magnetic latch, artwork, and label.	A white box made of cardboard, no magnetic latch and no artwork. The white box slides inside a sleeve that has artwork and label.	Different
Storage Case	The storage case contains a USB cable, charging dock, device, user manual, Instruction guide, and resealable bag consisting of electrodes	The storage case contains a USB, charging adapter, and electrode inside. The device is on a cardboard sheet on top of the storage case. User manual(s) are below the case.	Different
Number of electrodes provided with the device	Three (3)	One (1)	Different
Electrode storage	Resealable bag	Non- resealable bag	Different

5.6.4.1. Similarities between Subject Device and Predicate Device

- The intended use is the same for the Subject and the Predicate Devices and both devices are meant for Prescription use.
- Treatment Programs - Waveform characteristics and output specifications are same for both the Subject and Predicate Device.
- The Channels are the same for both the Subject and Predicate Devices.
- Maximum output voltage is the same for both Subject and Predicate Devices.
- Maximum output current is the same for both Subject and Predicate Devices.
- The Power source (Battery) is the same for both Subject and Predicate Devices.
- The Pulse duration, Maximum phase charge and Type of impedance monitoring system is the same for both Subject and Predicate devices.
- The dimensions and patient contacting material used in the electrode is same for both Subject and Predicate devices.

5.6.4.2. Differences between Subject Device and Predicate Device

- The RFID tag is added to electrode for Subject Device for electrode detection and, electrode metal plate thickness in Subject Device (1mm) is different from Predicate Device (0.4mm).
- The weight and dimensions of the Subject device is different from Predicate Device.

- The Audio and Visual Indication for low battery, bluetooth and electrode detection in the Subject device is different from Predicate device.
- The charging system in the Subject Device is different in terms of the design and the characteristics of input power. The Charging system of the Subject Device receives DC input from an AC/DC adapter while the charging system in the Predicate Device consists of an AC/DC adapter that receives AC input. However, both charging systems provide identical DC output voltage to the neurostimulator. The safety of the charging system in the Subject Device owing to the differences in design characteristics compared to that in the Predicate Device, is demonstrated by performance testing according to IEC 60601-1.
- The packaging configuration of Subject and Predicate devices are different. However, it does not raise new questions about safety and efficacy.

5.7. PERFORMANCE TESTING - BENCH

The following bench performance testing was carried out for the devices in the Cefaly® Dual series to evaluate the safety and efficacy of the devices due to the changes made over the Predicate Device:

Table 5.7.1 : List of Tests Performed - Cefaly® Dual Series

Testing Type	Test Description	Test Result
Electrical Safety and Electromagnetic Compatibility Testing	• IEC 60601-1:2005+ AMD 1 Edition 3.1, 2012-08 • IEC 60601-1-2 Edition 4.0	Electrical safety and EMC evaluation were performed on the Cefaly® Dual Series according to following FDA-recognized and other international standards.

	2014-02 ● IEC 60601-1-11 Edition 2.0 2015-01 ● IEC 60601-2-10 Edition 2.1 2016-04	

Adhesion testing was carried out to evaluate the adhesion performance of the Cefaly® electrodes when used with the Subject Devices. The test results demonstrated that the electrodes function as intended when used and replaced in accordance with the IFU, and that there are no new or different questions related to safety and efficacy of the Subject Device.

5.8. PERFORMANCE TESTING -ANIMAL

No animal testing was required to justify the differences with the corresponding Predicate Devices.

5.9. PERFORMANCE TESTING - CLINICAL

No clinical testing was required to justify the differences with the corresponding Predicate Devices.

5.10. COMPLIANCE WITH SPECIAL CONTROLS

Cefaly Technology complies with all applicable special controls for 21 CFR 882.5891. The special controls and corresponding compliance are listed below:

1. The patient-contacting components of the device must be demonstrated to be biocompatible - The material and manufacturing methods remain the same to that of the Predicate Devices, therefore the biocompatibility continues to be met as per K201895.

2. Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety - Electrical safety and Electromagnetic compatibility testing for Cefaly® Dual Series was

conducted in compliance with IEC 60601-1 and IEC 60601-1-2 standards and the results were found to be satisfactory.

3. The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2,000, and 10,000 ohm loads), pulse duration, frequency, net charge (µC) per pulse, maximum phase charge at 500 ohms, maximum current density (mA/cm2, r.m.s.), maximum average current (mA), maximum average power density (W/cm2), and the type of impedance monitoring system must be fully characterized - The Cefaly® Dual Series devices have an electrical impedance monitoring system. Characterization of all the required technical parameters of the device was provided, and verification and validation tests were performed in accordance with IEC 60601-2-10 for Cefaly® Dual Series devices.

4. Electrical performance, adhesive integrity, shelf life, reusability, and current distribution testing of the electrodes must be conducted - Electrical performance, adhesive integrity, reusability, and current distribution testing was conducted for Cefaly® Dual Series and the results were found to be satisfactory. Nothing that affects the shelf life of the Cefaly® Dual Series was changed, and the shelf life continues to be the same as that of the Predicate Devices.

5. Appropriate software verification, validation, and hazard analysis must be performed - Device Hazard Analysis and Software V&V were conducted for Cefaly® Dual Series and the results were found to be satisfactory.

6. Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population - Indications for use, intended patient population, and technological characteristics of the Subject Device remain unchanged as compared to the Predicate Devices. The differences between the Subject and the Predicate Devices do not have an impact on the clinical performance and it continues to be the same as that of the Predicate Devices.

7. Labeling for Cefaly® Dual Series devices includes the following:

a. Appropriate contraindications such as not for use in subjects with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator.

b. Appropriate warnings such as not to apply the device on the neck or chest, not to use the device in the presence of electronic monitoring equipment, not to use in the bath or shower, not to use while sleeping, not to use while driving, not to use while operating machinery

c. Appropriate precautions such as the long-term effects of chronic use of the device are unknown.

d. A summary of the expected risks and benefits of using the device.

e. A summary of the clinical performance data, including information on the patient population for which the device has and has not been demonstrated to be effective, and any adverse events and complications.

f. Information on how the device operates and the typical sensations experienced during treatment

g. A detailed summary of the device technical parameters .

h. An expiration date/shelf life for the electrodes and the number of times they can be reused.

i. Disposal instructions

For all the aforementioned (a through i) labeling requirements, appropriate information and instructions have been provided in the labeling of the Subject Device.

5.11. CONCLUSION

Cefaly® Dual Series is substantially equivalent to the Predicate Device Cefaly® Dual in terms of technological characteristics, system operating range and indications for use. CEFALY Technology has concluded that the performance data obtained by evaluation of the Subject Device to the international standards demonstrate the safety and effectiveness of the Subject Device and justify substantial equivalence with the corresponding Predicate Devices.