July 18, 2024

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

Re: K234029
Trade/Device Name: CEFALY Connected - OTC, CEFALY 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: June 18, 2024
Received: June 18, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234029

Device Name

CEFALY Connected - OTC, CEFALY Connected - Rx

Indications for Use *(Describe)*

Cefaly Connected - OTC is 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 Connected - Rx is 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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1. SUBMITTER'S INFORMATION

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Summary Prepared: Jul 18, 2024

2. DEVICE INFORMATION

Common/Usual name: Transcutaneous electrical nerve stimulator to treat headache

Trade Name: CEFALY Connected - OTC, and CEFALY Connected - Rx

Regulation Name: Transcutaneous electrical nerve stimulator to treat headache

Regulation Number: 21 CFR Part 882.5891

Regulatory Class: Class II

Classification Panel: Neurology

Product Code: PCC

3. PREDICATE DEVICE INFORMATION

The Predicate Device is listed in Table 1

Table 1 - Predicate Device

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Predicate Device Name	Manufacturer	Predicate Priority	510K Number	Regulatory Information
Cefaly® Dual Series (Cefaly® Dual Enhanced with RFID - Rx, Cefaly® Dual Enhanced with RFID - OTC, Cefaly® Dual Connected - Rx and Cefaly® Dual Connected - OTC)	CEFALY Technology	Primary	K212071	Regulation Name: Transcutaneous electrical nerve stimulator to treat headache Regulation Number: 21 CFR Part 882.5891 Regulatory Class: Class II Classification Panel: Neurology Product Code: PCC

The Predicate Device is not subject to recall by the FDA.

For this submission, the subject device has been compared with the Cefaly® Dual Connected - Rx and the Cefaly® Dual Connected - OTC of K212071, to demonstrate substantial equivalence.

4. DEVICE DESCRIPTION

CEFALY Connected - Rx and CEFALY Connected - OTC consists of neurostimulators, Cefaly Electrodes, and mobile application. The neurostimulators are small, non-invasive, and portable devices meant to be worn on the forehead using a self-adhesive electrode to treat migraines similar to Cefaly® Dual Connected - Rx, and Cefaly® Dual Connected - OTC of K212071.

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The mobile application, CeCe Migraine Management App, is a two-way communicating, mobile application, installed and run on users' personal mobile devices such as smartphone or tablet. The app is compatible with neurostimulators of CEFALY Connected devices (Rx and OTC). The mobile application communicates with the neurostimulator through Bluetooth and allows users to track the treatments.

This application software allows the users:

- to select a treatment mode (Acute/Prevent)
- to start or stop a treatment session
- to control treatment intensity
- to monitor treatment sessions in real-time including time elapsed, the neurostimulator's battery level, Bluetooth connection status
- to log preventative treatment data such as time/date, duration, and treatment intensity
- to maintain (log or record) migraine diary (information), where user can log migraine triggers and symptoms
- to view device status such as the device's battery level, connection state, and user notifications such as the following push notifications
    - reminders scheduled by the user to do a PREVENT treatment, track the treatment session, log a migraine episode
    - informs users when the intensity is ramping up and the intensity is stabilized.

All the above functions are available only to registered users who have successfully paired their neurostimulator.

The above functions are further elaborated below:

1. Selecting treatment mode

This feature allows the user to select the preferred treatment mode such as Acute or Preventative.

2. Starting/Stopping treatment

   This feature allows the user to initiate ACUTE or PREVENT treatment sessions alternatively, using the app user interface. Treatment sessions once initiated using the app can run and terminate independently of the app. The app also sends push notifications of treatment activity.

3. Controlling treatment intensity

   This function allows the user to, as an alternative to the control button on the neurostimulator, increase or stabilize treatment intensity and displays a real-time variation of the intensity level on the app user interface. The treatment control buttons operate exactly the same manner as the control button on the neurostimulator.

4. Monitoring Treatment session

   During a treatment session, users can view the treatment intensity graphically, the time remaining for the treatment session, the battery status of the CEFALY Connected Device paired with the smartphone, and the status of the Bluetooth Connection between the smartphone and the neurostimulator. The mobile application sends push notifications to the smartphone to inform them about active treatment sessions when the app is running in the background.

5. Logging Treatment information

   Users of the mobile application can record information about treatments undergone using both CEFALY Connected devices and other modes such as drugs. This information is used to create data points for visuals on migraine treatment information.

6. Logging Migraine information

   Users of the mobile application can record information related to

migraines experienced, such as symptoms, maximum pain intensity, migraine triggers, Location of pain, medication or non-drug treatments taken, overall treatment effectiveness, and additional notes about the treatment(s). This information is used to create data points for visuals on trends and patterns in the user's migraine journey.

7. Generating Insights/Trends

   This feature displays the graphical data that includes:

   - The three most common triggers over set time
   - Intensity of migraine over set time
   - Maximum intensity reached during preventative CEFALY sessions over a set time
   - Migraine frequency over set time
   - The average duration of migraine attacks over a set time
   - Treatment intensities over set time
   - Type of drug and non-drug treatment information logged by the user corresponding to the historical migraine attacks
   - Average effectiveness based on user-provided ratings each time they log historical migraine attacks

   The graphical data is generated based solely on user inputs, i.e., when users fill out the migraine logs and/or the preventative treatment logs.

8. Export to PDF

   This feature allows the following information regarding the health condition (based on user inputs)to be reported:

   - Patient-specific statistics related to existing migraine based on information collected during user registration on the application

- Trends based on Migraine triggers, location of pain, symptoms, frequency per day of the week, and intensity based on information collected during user registration on the application.
- Trends of Acute and Preventative treatments used during migraine attacks
- Evolution of the symptoms based on Migraine Frequency, Intensity, Average Duration, Acute and preventative Treatments, Average treatment Effectiveness over time
- Evolution of migraine treatments, triggers, and symptoms, based on categories such as top 3 Acute and Preventative treatments of migraine

Most of the device functions are the same as the device functions cleared in K212071. The changes made include adding more functions to the mobile application. The differences between the mobile application of the Subject Device and the version submitted in K212071 are as follows:

- The mobile application of the Subject Device has 2-way communication allowing the app to start/stop treatment sessions, and control (increase/stabilize) intensity as an alternative to the control button on the neurostimulator.
- Push notifications to users, suggesting them to undertake Prevent Treatment as scheduled by them and inform users when the intensity is ramping up and the intensity is stabilized
- Log historical preventative treatment data using the Cefaly device, namely time, date, duration, and treatment intensity, in addition to the acute treatment data using the Cefaly device

5. INDICATIONS FOR USE

Cefaly Connected - OTC is 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 Connected - Rx is 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

6. TECHNOLOGICAL CHARACTERISTICS

6.1. Comparison of Technological Characteristics between Subject and Predicate Devices

Comparison for the mobile application component			
Parameters	**Subject Device**	**Primary Predicate Device: Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
Device Physical status	Mobile Application	Mobile Application	Equivalent
Major app functionalities	• Remote treatment session control of hardware through Bluetooth interface • Treatment log • Migraine log	• Treatment log • Migraine log • PDF Download of trends and patterns	Different

Comparison for the mobile application component			
Parameters	**Subject Device**	**Primary Predicate Device: Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
	• PDF Download of trends and patterns		
User Interface: Treatment Session Controls	• Start/stop treatment sessions • Increase intensity • Stabilize intensity	No Treatment session controls available	Different
Monitoring treatment progress	Visually Monitor progress of treatment sessions through app user-interface in addition to the audio-visual indications on the hardware	Visually monitor progress of treatment sessions through app user-interface in addition to the audio-visual indications on the hardware	Equivalent
Treatment Logs	Patient-reported	Patient-reported	Equivalent
Migraine logs	Patient-reported	Patient-reported	Equivalent
Migraine report	PDF report consisting of trends and patient-specific statistics based on user	PDF report consisting of trends and patient-specific statistics based on user reported	Equivalent

Comparison for the mobile application component			
Parameters	**Subject Device**	**Primary Predicate Device: Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
	reported migraine information, acute and preventative treatments, which can be saved and shared with a healthcare provider	migraine information, acute and preventative treatments, which can be saved and shared with a healthcare provider	
User authentication	User authentication via account creation and login process	User authentication via account creation and login process	Equivalent
Graphical Data	Data graphs displaying number of migraines experienced, migraine pain intensity, location, symptoms, triggers, drug/ non-drug treatments, frequency of treatments, distribution of migraines across a specified timeframe (months, weeks, etc.), trends in triggers, medications reported, and treatment intensity of	Data graphs displaying number of migraines experienced, migraine pain intensity, location, symptoms, triggers, drug/ non-drug treatments, frequency of treatments, distribution of migraines across a specified timeframe (months, weeks, etc.), trends in triggers, medications reported, and treatment intensity of CEFALY treatment sessions	Equivalent

Comparison for the mobile application component			
Parameters	**Subject Device**	**Primary Predicate Device: Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
	CEFALY treatment sessions		
Indicators on app interface	Visual (textual indicators in form of pop-ups, banners, push notifications, information display) indicators for: 1. On/off status 2. Battery charge status in terms of remaining charge 3. Bluetooth Connection state 4. Type of treatment program selected during initial selection 5. Time remaining for a treatment session to end	Visual (textual indicators in the form of pop-ups, banners, push notifications, information display) indicators for: 1. On/off status 2. Battery charge status in terms of remaining charge 3. Bluetooth Connection state 4. Type of treatment program selected throughout treatment session 5. Time remaining for a treatment session to end 6. When the treatment is	Different

Comparison for the mobile application component			
Parameters	**Subject Device**	**Primary Predicate Device: Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
	6. Intensity stabilized 7. Intensity ramp-up 8. Intensity at 10 mA 9. Intensity at maximum value 10. Reminders to do Prevent Treatment as scheduled by user	in session	
Option to Log historical preventative treatment data using the Cefaly Device	Available	Unavailable	Different

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Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and,** **Cefaly® Dual Connected -Rx**	**Equivalence**
Device button functions	• Start treatment sessions • Increase intensity • Stabilize intensity • Initiate Bluetooth connection	• Start Treatment sessions • Increase intensity • Stabilize intensity • Initiate Bluetooth connection	Equivalent
Bluetooth	Yes	Yes	Equivalent
Charging System	Charging dock, Power adapter and USB Cable.	Charging dock, Power adapter and USB Cable.	Equivalent
Power Source	1 rechargeable LiPo	1 rechargeable LiPo	Equivalent

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Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and,** **Cefaly® Dual Connected -Rx**	**Equivalence**
	3.7 V battery	3.7 V battery	
Weight	25 grams	25 grams	Equivalent
Dimensions	66 mm x 47 mm x 17 mm	66 mm x 47 mm x 17 mm	Equivalent
Channels	1	1	Equivalent
Treatment Programs	2 programs: ● Program 1 - The acute treatment of Migraine attacks ● Program 2 - The prevent treatment of	2 programs: ● Program 1 - The acute treatment of Migraine attacks ● Program 2 - The prevent treatment of	Equivalent

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Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and,** **Cefaly® Dual Connected -Rx**	**Equivalence**
	migraine	migraine	
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	8	8	Equivalent

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Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
At 2,000 ohms At 10,000 ohms	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

Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and,** **Cefaly® Dual Connected -Rx**	**Equivalence**
Maximum current density (mA/cm2 , 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)	0.000047	0.000047	Equivalent

Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and,** **Cefaly® Dual Connected -Rx**	**Equivalence**
at 500 ohms			
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/cm2) at 500 ohms	0.000017	0.000017	Equivalent
Audio-visual Indications			

Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
Audio Indicators for low battery, Type of treatment program selected, Acute and Prevent Program (Low Battery Charge), Intensity is 10mA, Stabilized intensity, Maximum Intensity reached, Increase Intensity (For Experienced CEFALY Users), Bluetooth connection and disconnection and electrode detection	Present	Present	Equivalent
Visual Indicators for low battery, Type of treatment program selected,	Present	Present	Equivalent

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Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and,** **Cefaly® Dual Connected -Rx**	**Equivalence**
fully charged battery, battery charging, bluetooth connection and disconnection and electrode detection			
Electrode			
Dimensions	94 mm x 20 mm	94 mm x 20 mm	Equivalent
Electrode Gel used	Acrylic Hydrogel	Acrylic Hydrogel	Equivalent
Packaging configuration			
Gift Box	Made of cardboard, has a magnetic latch, artwork, and label.	Made of cardboard, has a magnetic latch, artwork, and label.	Equivalent
Storage Case	The storage case contains a USB cable, charging dock, device, user manual, Instruction guide,	The storage case contains a USB cable, charging dock, device, user manual, Instruction guide, and	Equivalent

Comparison for the neurostimulator used with the Subject Device and the Predicate Device			
Parameters	**Subject Device**	**Primary Predicate Device:** **Cefaly® Dual Connected - OTC, and, Cefaly® Dual Connected -Rx**	**Equivalence**
	and resealable bag consisting of electrodes	resealable bag consisting of electrodes	
Number of electrodes provided with the device	Three (3)	Three (3)	Equivalent
Electrode storage	Resealable bag	Resealable bag	Equivalent

6.2. Substantial Equivalence Discussion

6.2.1. Similarities between Subject Device and it's Predicate

The following technological characteristics are identical between Subject Device and Predicate Devices;

- Device physical status, as both the Subject Device and Predicate Devices have software applications deployed on commercially available smartphones
- User authentication
- Treatment Logs record the same information in case of both Subject and Predicate Devices

- Migraine logs record the same information in case of both Subject and Predicate devices
- Migraine report record the same trends and patterns in both the Subject and Predicate Devices
- Graphical data - Same data graphs based on user-provided information is presented
- The same Bluetooth protocol is used for the neurostimulator used with the Subject and in the Predicate Device.
- The power source, the charging system, and mechanical characteristics are the same for the neurostimulator in the case of both the Subject and the Predicate Device.
- Waveform characteristics and output specifications of both ACUTE (Program 1) and PREVENT (Program 2) are the same for both the Subject and the Predicate Device.
- Audio-visual Indications and Device button functions used in the neurostimulators for both the Subject and Predicate devices, are the same.
- The packaging configuration and patient-contacting component of the Electrode used with the Subject and Predicate Device are the same.

6.2.2. Differences between Subject Device and it's Predicate

Following are the differences in the technological characteristics of the Subject and Predicate Device:

- Major App functionalities

  The only difference between the Subject and Predicate Device is that the mobile application of the Subject Device has 2-way communication enabling remote control of the

neurostimulator. The mobile application is intended for use as an accessory to the neurostimulator, which is the same for both the Subject Device and the Predicate Device given that:

1. The Neurostimulator can perform treatment sessions independent of the mobile application,

2. Software - user interface provided by the mobile application of the Subject Device is supplementary to that of the neurostimulator and can be overridden by the latter.

There are no new questions of safety and efficacy. This is further substantiated by the risk analysis and the Non-clinical Bench Performance testing.

The remaining mobile app functions as cited in the technological comparison of the mobile application component, are identical in the case of the Subject and the Predicate Device, are non-medical ("other") device functions, and as discussed in the device description, do not have any impact on the medical device function (controlling the hardware).

- Treatment Session Controls:

  The mobile application component in the Subject Device includes different control functions. In the case of the Predicate device, the mobile application component did not include any functionalities to control the neurostimulator.

  In the Subject Device, the user controls in the mobile application component (functions related to increasing intensity, starting treatment, and stabilizing treatment) are consistent (function in the same way, i.e., long press

for ramp-up, increasing/stabilizing within the first 14 minutes of starting the treatment, etc.) with the technological characteristics of neurostimulator component, and have been validated through software system validation and interoperability testing.

For the Subject Device, the only additional (device button vs app button) treatment session control provided with the mobile application component is the "Stop" button in the app. This button allows the user to prematurely terminate an active treatment session that is initiated from the app. In the case of Predicate Device, the user had the only option to manually detach the device from the electrode for premature interruption of an active session initiated from the device. However, the manual detachment and the "Stop" button have the same function, that is, prematurely terminate the treatment. Thus, no new questions of safety or efficacy are raised.

Furthermore, given that the control functions provided with the mobile application and the neurostimulator component of the Subject Device are independent of each other and the user can override the app controls using the neurostimulator controls, it makes the app controls only supplementary, thus not raising different questions of safety or efficacy.

- Monitoring treatment Progress

  Given that the mobile app is intended to be used as an accessory that supplements, in this case, the user-interface of the neurostimulator, and does not override the audio-visual indicators provided by the neurostimulator, there are no conflicts regarding the indications for the treatment progress for the user, during an active treatment session. The user can use indicators

from either or both the neurostimulator and mobile application to review the treatment progress. Furthermore, given that the neurostimulator can still indicate (due to independent functioning, i.e., not needing the app to be active throughout a treatment session) treatment progress in the event of the app malfunctioning, there are no new questions of safety or efficacy.

- Types of indicators on app interface

  The differences between the Subject and Predicate Devices are in terms of

  1. Type of indications provided for informing the user about the type of treatment program selected or activated - In the Subject Device, the mobile app allows the user to select the type of treatment session. The selection made through a pop-up thus informs the user about the Acute or Preventative session, as the user taps the app button textually displaying the name of the session. However, once the selection through the mobile app is made, the type of session selected is indicated only by the visual indication on the neurostimulator. The mobile app in the case of Predicate Device, however, constantly displays the name of the treatment session in addition to the visual indicator on the neurostimulator, throughout the session's duration.

     Given that the user is made aware of the type of treatment selected throughout the session, by the same visual indication on the neurostimulator in the case of both Subject and Predicate devices, there are no new safety or efficacy questions due to the use of the mobile app as an accessory.

2. Indications to inform active session - In the case of mobile application of the subject device there are no indications for an active session. However, there are push notifications to inform the user in case the app is running in the background for a predefined amount of time, which while acting as a supplementary indication, also ensures that there are no safety hazards as a result of the user becoming dependent on the mobile app user interface in a home environment. There are similar push notifications for the Intensity related controls as discussed in the device description.

3. Reminder to perform prevent session - The mobile application of the Subject Device includes a reminder functionality for Preventative sessions. The user can set reminders for themselves to perform preventative treatment sessions, which is displayed by the app, accordingly as a reminder to the user. The application does not analyze user provided information to suggest the reminders. As this functionality is based on the user's inputs and is a non-medical device function, there are no new questions of safety and effectiveness.

- Option to log historical preventative treatment data using the Cefaly device

  The mobile application of the subject device allows the user to log historical data for treatment using Cefaly device, for both Acute and Preventative sessions. The Predicate Device allowed logging only Acute treatment sessions performed using the Cefaly device. This is a non-medical device function, and thus does not raise any questions of safety and effectiveness.

7. PERFORMANCE TESTING - BENCH

Software Verification and Validation, including interoperability testing, was performed per the Software Test Plan to validate the control functions and associated features of the mobile app. Results of the testing were recorded in a test report, which demonstrates that the user interface provided by the application is consistent with the intended use of the device cleared under K212071.

Bench testing was performed to evaluate interoperability. The testing demonstrated that the intensity values displayed by the app and the actual intensity values are almost the same with an acceptable tolerance limit (-2%). It also demonstrates that the Bluetooth interface does not introduce unacceptable latency between the device and the mobile application. The Electromagnetic compatibility of CEFALY Connected and the safety of the wireless functions were demonstrated in K212071.

Threat modeling and penetration testing were done to identify security threats. Control measures were applied accordingly and traceability between the measures and the identified security threats was documented in a cybersecurity report.

8. PERFORMANCE TESTING -ANIMAL

No animal studies have been conducted for the Subject Device.

9. PERFORMANCE TESTING - CLINICAL

No clinical studies have been conducted for the Subject Device.

10. COMPLIANCE WITH SPECIAL CONTROLS

Cefaly Technology complies with all applicable special controls for 21 CFR Part 882.5891.

The following special controls are directly addressed and re-verified in this submission:

1. Appropriate software verification, validation, and hazard analysis must be performed - See section 7, Performance Testing - Bench and section 11, Conclusion.

2. Labeling for CeCe Migraine Management App includes the following:

    a. Information on how the device operates and the typical sensations experienced during treatment - The relevant information has been included in the labeling.

The following special controls were addressed in K212071:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety

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.

4. Electrical performance, adhesive integrity, shelf life, reusability, and current distribution testing of the electrodes must be conducted.

5. Appropriate software verification, validation, and hazard analysis must be performed.

6. Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population.

7. Labeling for the neurostimulators (See K212071) 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. Information on how the device operates and the typical sensations experienced during treatment

    h. A detailed summary of the device's technical parameters.

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

    j. 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.

11. CONCLUSION

The Subject Device is believed to be substantially equivalent to the Predicate Device based on the results of risk assessment, software validation, and interoperability tests. The risk assessment evaluates the hazards associated with the medical device, non-medical device functions, interoperability, and cybersecurity. The risk assessment also demonstrates that the non-medical device ("other") functions of the mobile application do not affect the safety and efficacy of the medical device functions associated with the Subject Device.

The software validation evaluates the intended functioning of the user interface associated with treatment controls in the mobile app and demonstrates that the controlling functions of the mobile app are the same as the physical controls provided by the neurostimulator, and are safe and effective. Bench testing and software validation, together validate the Bluetooth Interface functioning and substantiate that the treatment controls using the mobile app are not affected by the interface. The existing wireless coexistence results demonstrate that there are no new hazards arising from the use of the Subject Device in a home environment.

The results of these evaluations demonstrate that new questions of safety and efficacy are not raised due to the technological differences between the Subject and Predicate Devices, resulting in the Subject Device being substantially equivalent to the Predicate Device.