October 5, 2021

Cala Health, Inc.
Danielle Boyd
Director, Regulatory Affairs
875 Mahler Road, Suite 168
Burlingame, California 94010

Re: K203288
Trade/Device Name: Cala Trio
Regulation Number: 21 CFR 882.5897
Regulation Name: External upper limb tremor stimulator
Regulatory Class: Class II
Product Code: QBC
Dated: November 6, 2020
Received: November 9, 2020

Dear Danielle Boyd:

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,

Patrick Antkowiak
Acting 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)*
K182706

Device Name
Cala Trio

Indications for Use *(Describe)*
The Cala Trio device is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
510(k): Device Modification [K203288]

I. Submitter

Manufacturer: Cala Health, Inc.
875 Mahler Rd, Suite 168
Burlingame, CA 94010
Phone: (415) 890-3961
Fax: None

Primary Contact: Danielle McDonnell Boyd
Director, Regulatory Affairs, Cala Health
danielle@calahealth.com
(415) 819-2935

Date Prepared: October 4, 2021

II. Subject Device

Trade Name: Cala Trio™

Classification Name: External upper limb tremor stimulator

Device Classification: Class II

Regulation: 21 CFR 882.5897

Product Code: QBC

III. Predicate Device

Predicate Device: Cala ONE

Prior Submissions: DEN170028, K182706

Indications for Use: Cala ONE is indicated to aid in the transient relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

IV. Description of Device

Cala Trio is a small, lightweight, wrist-worn stimulator device designed to aid in essential tremor symptom relief by applying Transcutaneous Afferent Patterned Stimulation (TAPS) to the median and radial nerves of a patient's wrist. The Cala Trio system includes three main components: (1) a rechargeable stimulator, (2) a wrist-worn electrode band, and (3) a base station that charges the device.

The stimulator component contains the electronics for delivering TAPS to the patient's wrist. There are three buttons on the stimulator that are used for calibration and stimulation amplitude adjustments, among other functions. Text prompts, stimulation delivery parameters, timer, and other messages are provided on the stimulator's full color display to provide instructions and stimulation delivery information.

To deliver therapy, the stimulator is attached to the wrist band, which includes integrated electrodes placed at appropriate intervals around the inner diameter of the band to properly target the median and radial nerves. To accommodate a broad distribution of wrist sizes, the band is available in three sizes (small, medium, and large). Each band size is also available in right or left-handed versions to target the appropriate nerves of the prescribed hand.

V. Indications for Use

Cala Trio is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

VI. Technological Characteristics

The following table provides a summary comparison for technical characteristics between Cala ONE (predicate device) and Cala Trio (subject device).

Technical Comparison of the Subject Device and Predicate Device

	Cala ONE **DEN170028** **K182706** **(Predicate Device)**	**Cala Trio** **K203288** **(Subject Device)**	**Discussion of Differences**
Intended Use	Delivery of transcutaneous afferent patterned stimulation (TAPS) for hand tremors in essential tremor patients	Delivery of transcutaneous afferent patterned stimulation (TAPS) for hand tremors in essential tremor patients	Same
Indications for Use	Cala ONE is indicated to aid in the transient relief of hand tremors in adults with essential tremor.	Cala Trio is indicated to aid in the temporary relief of hand tremors in adults with essential tremor.	Substantially Equivalent *The indications for use is changed from "transient" to "temporary" but does not impact safety or effectiveness. Cala Trio is indicated for the same condition and patient population.* *Clinical evidence summarized in Section VII demonstrates that the indications for use change does not impact the safety or effectiveness of the device.*

	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Discussion of Differences
Design	Stimulator with on- board motion sensors permanently mounted on wristband	Stimulator with on- board motion sensors that is detachable from wristband	Substantially Equivalent *The difference in component attachment does not impact the safety or effectiveness of the device.* *The TAPS therapy parameters as controlled by Cala Trio are unchanged from Cala ONE.*
	Wrist-worn band with three 4x4 cm^2 electrodes manually attached by the user	Wrist-worn band with three 4.84 cm^2 electrodes embedded in the band	Substantially Equivalent *The difference in electrode configuration does not impact the safety or effectiveness of the device.* *Clinical evidence summarized in Section VII demonstrates that the surface area change does not impact the safety or effectiveness of the device.* *The Cala Trio electrode surface area is equivalent and the electrode material are unchanged from Cala ONE.*

	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Discussion of Differences
	AC-powered charger that connects to the stimulator via USB port	AC-powered base station for recharging the stimulator Base Station includes an LTE antenna that provides connection and data transfer to cloud system which supports device operations such as device assistance and maintenance	Substantially Equivalent *The difference in the charging component does not impact the safety or effectiveness of the device.* *The Cala Trio energy source (battery) and stimulator circuitry is unchanged from Cala ONE.* *The cloud provides support and maintenance functions only. Transferred data is used for monitoring purposes only and is not used for diagnosis or other treatment-related recommendations or treatment adjustments.*
	Embedded firmware control of device calibration, stimulation delivery, and device function	Embedded firmware control of device calibration, stimulation delivery, and device function	Same

	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Discussion of Differences
	Device sensors (gyroscope and triaxial accelerometer) measure tremor motion	Device sensors (triaxial accelerometer) measure tremor motion	Substantially Equivalent *The difference in the motion sensors does not impact safety or effectiveness.* *Non-clinical performance testing demonstrated that the measurements obtained from the Cala Trio sensor are equivalent to those obtained from the Cala ONE sensors.*
Features	• Set-up calibration • Stimulation intensity control • Therapy available on demand	• Set-up calibration • Stimulation intensity control • Therapy available on demand	Same
User Interface	Stimulator display guides device setup, operation, and usage information. Four buttons on the device housing allow user control of the stimulation amplitude and device calibration	Stimulator display guides device setup, operation, and usage information. Three buttons on the device housing allow user control of the stimulation amplitude and device calibration	Substantially Equivalent *The difference in the user interface does not impact safety or effectiveness.* *The Cala Trio buttons serve the same combined functions as those controlled separately by the buttons in Cala ONE. The device setup, operation, and usage information are unchanged.*
Prescription or OTC	Prescription	Prescription	Same
Sterility	Non-sterile	Non-sterile	Same
Materials	Biocompatible wrist band	Biocompatible wrist band	Same

	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Discussion of Differences
Energy Source	Permanent 3.7V Lithium-Ion rechargeable battery	Permanent 3.8V Lithium-Ion rechargeable battery	Substantially Equivalent *The difference in battery voltage does not impact safety or effectiveness.* *The Cala Trio and Cala ONE device batteries both comply with IEC 62133 standard.*
Frequency of Use	The device is used as needed by the patient	The device is used as needed by the patient	Same
Band Use Life	Single Use (DEN170028) 30 Days (K182706)	90 Days	Substantially Equivalent *The difference in band use-life does not impact safety or effectiveness.* *Non-clinical performance testing demonstrated that the Cala Trio electrode maintains electrode integrity and delivers therapy as intended for the duration of the 90-day use-life.*
Principle of Operations	Biphasic Waveform, rectangular	Biphasic Waveform, rectangular	Same
Output Modes	1 channel with 2 alternating outputs	2 alternating channels	Substantially Equivalent *The difference in the number of output channels does not impact safety or effectiveness.* *The functionality of the output channel and the therapy parameters are unchanged.*

	Cala ONE **DEN170028** **K182706** **(Predicate Device)**	**Cala Trio** **K203288** **(Subject Device)**	**Discussion of Differences**
Output	Current Regulated	Current Regulated	Same
Housing Materials	Plastic Velcro Straps (Nylon)	Plastic Velcro Straps (Nylon)	Same
Weight	56g	Stimulator: 28g Base Station: 209g Band: 13.4g – 15.9g	Substantially Equivalent *The difference in device weight does not impact safety or effectiveness.* *The total weight of the patient-worn components of Cala Trio and Cala ONE (band and stimulator) have equivalent weights.*
Dimensions (mm)	52 x 79 x 16	Stimulator: 42 x 55 x 13 Base Station: 104 x 36 x 91 Band Length: 252.5 - 327.5 Band Width: 20.8 -54.1	Substantially Equivalent *The difference in device dimensions does not impact safety or effectiveness.* *The patient-worn components) of Cala Trio and Cala ONE (band and stimulator) have equivalent dimensions*

VII. Performance and Non-Clinical Testing

The following tables provide a summary comparison for performance, and nonclinical testing of Cala ONE (predicate device) and Cala Trio (subject device).

Performance Comparison of the Modified Device and Predicate Device

Output Specification Category	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Comparison Result
Waveform	Biphasic	Biphasic	Same
Shape	Rectangular	Rectangular	Same
Maximum Output Voltage (volts)	7.5 @ 500Ω	7.5 @ 500Ω	Same
	120 @ 10kΩ	80 @ 10kΩ	Substantially Equivalent *The therapy pattern parameters are unchanged.* *Clinical evidence summarized in Section VII demonstrates that the reduction in maximum output voltage does not impact safety or effectiveness of the device*
Maximum Output Current (mA)	15 @ 500Ω	8 @ 500Ω	Substantially Equivalent *The therapy pattern parameters are unchanged.* *Clinical evidence summarized in Section VII demonstrates that the reduction in maximum output current does not impact safety or effectiveness of the device*
	12 @ 10kΩ	8 @ 10kΩ	

Output Specification Category	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Comparison Result
Duration of primary (depolarizing) phase (µsec)	300	300	Same
Pulse Duration (µsec)	650	650	Same
Frequency (Hz)	150	150	Same
Symmetrical phases?	Yes	Yes	Same
Phase Duration (µS)	300 each phase	300 each phase	Same
Net Charge (µC)	0 @500Ω	0 @500Ω	Same
Maximum Phase Charge (µC)	4.5 @ 500Ω	2.4 @ 500Ω	Substantially Equivalent *The therapy pattern parameters are unchanged.* *Clinical evidence summarized in Section VII demonstrates that the reduction in maximum phase charge does not impact safety or effectiveness of the device*

Output Specification Category	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Comparison Result
Maximum Current Density (mA/cm², r.m.s.)	2.41 @ 500Ω	1.17 @ 500Ω	Substantially Equivalent *The therapy pattern parameters are unchanged.* *Clinical evidence summarized in Section VII demonstrates that the reduction in maximum current density does not impact safety or effectiveness of the device*
Maximum Average Current (mA) (average absolute value)	1.35 @ 500Ω	0.72 @ 500Ω	Substantially Equivalent *The therapy pattern parameters are unchanged.* *Clinical evidence summarized in Section VII demonstrates that the reduction in maximum average current does not impact safety or effectiveness of the device*

Output Specification Category	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Comparison Result
Maximum Average Power Density (mW/cm²)	2.30 @ 500Ω	1.12 @ 500Ω	Substantially Equivalent *The therapy pattern parameters are unchanged.* *Clinical evidence summarized in Section VII demonstrates that the reduction in maximum average power density does not impact safety or effectiveness of the device*

Nonclinical Testing Comparison of the Modified Device and Predicate Device

Output Specification Category	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Comparison Result
Biocompatibility	Demonstrated Biocompatibility in accordance with ISO 10993-1:2009	Demonstrated Biocompatibility in accordance with ISO 10993-1:2018	Same
EMC and Electrical Safety	Meets all requirements of IEC60601-1 and relevant collateral and particular standards	Meets all requirements of IEC60601-1 and relevant collateral and particular standards	Same
Stimulation Waveform Testing	Stimulation waveform conforms to requirements of internal standard test method and acceptance criteria	Stimulation waveform conforms to requirements of internal standard test method and acceptance criteria	Same

Output Specification Category	Cala ONE DEN170028 K182706 (Predicate Device)	Cala Trio K203288 (Subject Device)	Comparison Result
Shelf Life Testing	Electrode performance conforms to requirements of internal standard test method and acceptance criteria at T=24 months	Electrode performance conforms to requirements of internal standard test method and acceptance criteria at T=24 months	Same

VIII. Clinical

The following clinical evidence was used to support the change in the indications for use:

- In an end-of-study survey following three months of repeated home use in Essential Tremor (ET) patients, 64% of the 205 patients who completed the study self-reported persistent tremor relief after the 40 minutes of stimulation lasting on average 94 minutes (standard deviation = 138; median = 60). (Isaacson, S. H. et al. (2020) "Prospective home-use study on noninvasive neuromodulation therapy for Essential Tremor," *Tremor Other Hyperkinet. Mov*., 10(1): 29, pp.-6 | doi: 10.5334/tohm.59).

- A study on 15 participants with ET who completed an in-office, single session study that measured tremor relief during stimulation, immediately after stimulation, and up to an hour after the end of stimulation demonstrated tremor relief after stimulation for 60 minutes for 70-80% of TAPS users (Yu, J. et al. (2020). "Transcutaneous afferent patterned stimulation therapy reduces hand tremor for one hour in essential tremor patients," *Front. Neurosci*., Vol. 14, pp. 1- 9 | doi: 10.3389/fnins.2020.530300)

The following clinical evidence was used to support the change in electrode surface area and reduction in output stimulation intensity:

- A prospective, multi-center, single-arm three months study of repeated home use of the Cala TRIO device (263 enrolled subjects with 205 subjects completing the study) in ET patients demonstrated results consistent with the original clinical study supporting the granting of DEN170028 for the Cala ONE. Results demonstrated that 62% (TETRAS) and 68% (BF-ADL) of 'severe' or 'moderate' patients improved to 'mild' or 'slight'. Clinicians (CGI-I) reported improvement in 68% of patients, 60% (PGI-I) of patients reported improvement, and QUEST improved. (Isaacson, S. H. et al. (2020) "Prospective home-use study on noninvasive neuromodulation therapy for Essential Tremor," *Tremor Other Hyperkinet. Mov.*, 10(1): 29, pp.-6 | doi: 10.5334/tohm.59).

IX. Substantial Equivalence

Substantial equivalence of Cala Trio to Cala ONE is demonstrated based on the comparison of technical characteristics, performance, and clinical and nonclinical testing. In summary:

- The intended use is unchanged but the indications for use has changed and has been supported by clinical data as described above.,
- Cala has provided the following evidence to demonstrate that any differences in labeling, technological characteristics, or materials do not impact safety or effectiveness (see Sections VII and VII above for additional detail):
  - The Cala Trio labeling contains all content per the Special Controls identified for external limb tremor stimulators per 21 CFR 882.5897
  - Clinical performance testing as described in Section VIII above
  - Non-clinical performance testing confirmed the following:
    - Electrical stimulation characterization
    - Electrode impedance testing and shelf-life
    - Sensor performance and associated algorithms
  - Biocompatibility testing demonstrates that both Cala ONE and Cala Trio meet the ISO 10993-1 standard and are therefore substantially equivalent with respect to biocompatibility.
- EMC and Electrical Safety testing demonstrates that Cala ONE and Cala Trio are compliant with the same applicable IEC 60601 clauses and are substantially equivalent with respect to Electrical Safety and EMC considerations.
- Stimulation waveform testing demonstrates that Cala ONE and Cala Trio produce a stimulation output that meets the same internal testing and acceptance criteria and are substantially equivalent with respect to stimulation output.
- Real time aging and performance testing of Electrodes demonstrate that both Cala ONE and Cala Trio bands meet the same performance requirements at 24 months and are substantially equivalent with respect to shelf life.

X. Conclusion

In summary, Cala ONE and Cala Trio are substantially equivalent. Cala has provided evidence as described above to demonstrate that any differences in the indications for use and technological characteristics do not impact safety or effectiveness.