January 16, 2025

Cala Health, Inc.
% Amanda Johnston
Regulatory Counsel for Cala Health, Inc.
Gardner Law PLLC
432 Main Street
Stillwater, Minnesota 55082

Re: K243848
Trade/Device Name: Cala kIQ
Regulation Number: 21 CFR 882.5897
Regulation Name: External upper limb tremor stimulator
Regulatory Class: Class II
Product Code: QBC
Dated: December 6, 2024
Received: December 16, 2024

Dear Amanda Johnston:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243848

Device Name

Cala kIQ

Indications for Use *(Describe)*

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

Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's disease.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

K243848

I. SUBMITTER

Manufacturer: Cala Health, Inc.
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Phone: (415) 890-3961
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Date Prepared: December 13, 2024

II. SUBJECT DEVICE

Trade Name: Cala kIQ™

Regulation Name: External upper limb tremor stimulator

Regulatory Class: Class II

Regulation Number: 21 CFR 882.5897

Product Code: QBC

III. PREDICATE DEVICE

Predicate Device: Cala kIQ™

Prior Submissions: K242259

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

Cala kIQ is indicated to aid in the temporary relief of postural and

kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's disease.

IV. DEVICE DESCRIPTION

Cala kIQ is a small, lightweight, wrist-worn stimulator device designed to aid in the temporary relief of hand tremors for patients with essential tremor and to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's disease. Cala kIQ is made up of three (3) components:

1. Cala kIQ Stimulator
2. Cala kIQ Band
3. Cala kIQ Base Station

Cala kIQ detects the frequency of a patient's tremor using on-board motion sensors and applies transcutaneous afferent patterned stimulation (TAPS), a constant current, charge-balanced waveform that alternates between the median and radial nerves of the wrist. The TAPS pattern is customized to the individual user through an automated device calibration, performed at device set-up.

Cala kIQ is only available via prescription. When Cala kIQ is prescribed for a patient, the ordering physician identifies a prescribed "tremor task," a tremor-inducing postural hold for the patient. The prescribed tremor task is performed by the patient during device calibration. Initial calibration is completed either in a patient's home or physician's office and is operated thereafter by the patient in a home-use setting. Calibration is completed only once for the initial set-up of the device. In addition, the tremor task is performed before and after sessions to measure changes in the patient's tremor amplitude. The patient is prompted on the device for these measurements for the first forty sessions and every seventh session thereafter.

V. INDICATIONS FOR USE

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

Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's Disease.

VI. COMPARISON WITH THE PREDICATE DEVICE

The subject device has the same intended use as the predicate device. The subject device has the same indications for use, control mechanisms, principles of operation, and energy type as the legally marketed predicate device, Cala kIQ (K242259).

The design difference between the subject device and the predicate device is the formulation of the proprietary electrode material. In addition, the shelf-life of the Band is different between the subject device and the predicate device. With the exception of the electrode material and shelf-life, the subject device has identical technological characteristics as the predicate device.

Table 1. Cala kIQ Substantial Equivalence

Category	Predicate Device	Subject Device	Substantially Equivalent?
510(k) Number	K242259	This submission	
Manufacturer	Cala Health	Cala Health	
Intended Use			
Intended Use	Delivery of transcutaneous afferent patterned stimulation ("TAPS") for treatment of hand tremors	Delivery of transcutaneous afferent patterned stimulation ("TAPS") for treatment of hand tremors	Yes Subject Device is identical to Predicate Device
Indications for Use	Cala kIQ is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's disease.	Cala kIQ is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living in the treated hand following stimulation in adults with Parkinson's disease.	Yes Subject Device is identical to Predicate Device
Target Population	Adults with essential tremor or Parkinson's Disease	Adults with essential tremor or Parkinson's Disease	Yes Subject Device is identical to Predicate Device
Anatomical site	Median and radial nerves	Median and radial nerves	Yes Subject Device is identical to Predicate Device

Category	Predicate Device	Subject Device	Substantially Equivalent?
Intended Users	Patient	Patient	Yes Subject Device is identical to Predicate Device
Clinical Setting	In-home use after an initial calibration in the patient's home or in the physician's office.	In-home use after an initial calibration in the patient's home or in the physician's office.	Yes Subject Device is identical to Predicate Device
Rx or OTC use	Prescription Use only	Prescription Use only	Yes Subject Device is identical to Predicate Device
Design			
Technology	Transcutaneous afferent patterned stimulation (TAPS) delivered through electrodes embedded on wearable band	Transcutaneous afferent patterned stimulation (TAPS) delivered through electrodes embedded on wearable band	Yes Subject Device is identical to Predicate Device
Energy used or delivered	Electrical stimulation	Electrical stimulation	Yes Subject Device is identical to Predicate Device
Human Factors	Wrist-worn electrical stimulator with detachable wristband containing re-usable electrodes. Separate Base Station provides charging function and data transfer	Wrist-worn electrical stimulator with detachable wristband containing re-usable electrodes. Separate Base Station provides charging function and data transfer	Yes Subject Device is identical to Predicate Device

Category	Predicate Device	Subject Device	Substantially Equivalent?
Patient Contacting Materials	The following components of the Cala kIQ Band have Surface, Intact Skin Long-Term contact (>30 days): • Electrodes (silicone with carbon nanotube dispersion) • Elastic (polyester with spandex) • Band thread (cotton) • Band silicone body • Band hook (sabic PC/ABS) • Stimulator bottom (PC/ABS)	The following components of the Cala kIQ Band have Surface, Intact Skin Long-Term contact (>30 days): • Electrodes (silicone with carbon nanotube dispersion) • Elastic (polyester with spandex) • Band thread (cotton) • Band silicone body • Band hook (sabic PC/ABS) • Stimulator bottom (PC/ABS)	Yes All patient-contacting materials are biocompatible per ISO-10993.
Operating Principle	Transcutaneous Afferent Patterned Stimulation (TAPS) to the median and radial nerves of a patient's wrist	Transcutaneous Afferent Patterned Stimulation (TAPS) to the median and radial nerves of a patient's wrist	Yes Subject Device is identical to Predicate Device
Electrodes	6 <u>Individual Electrode Surface area</u> 22mm x 6mm = 1.32 cm^2	6 <u>Individual Electrode Surface area</u> 22mm x 6mm = 1.32 cm^2	Yes Subject Device is identical to Predicate Device
Battery and Base Station	Rechargeable Lithium-ion battery and AC-powered charger.	Rechargeable Lithium-ion battery and AC-powered charger.	Yes Subject Device is identical to Predicate Device
Performance			
User Workflow	1. Calibration (completed at device setup only) 2. Set stimulation intensity 3. Therapy available on demand	1. Calibration (completed at device setup only) 2. Set stimulation intensity 3. Therapy available on demand	Yes Subject Device is identical to Predicate Device
Treatment Time	40 minutes	40 minutes	Yes Subject Device is identical to Predicate Device

Category	Predicate Device	Subject Device	Substantially Equivalent?
Wristband life	90 days	90 days	Yes Subject Device is identical to Predicate Device.
Shelf-life	Cala kIQ Band: 18 months	Cala kIQ Band: 3 months	Yes In K242259, Cala received FDA clearance to extend the shelf life of its current bands to 18 months. However, with the introduction of the new electrode material, we propose reverting to a 3-month shelf life until we complete the necessary testing to support the increase in shelf life.
Output Specifications			
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Yes Subject Device is identical to Predicate Device
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Yes Subject Device is identical to Predicate Device
Maximum Output Voltage (volts)	4 @ 500Ω	4 @ 500Ω	Yes Subject Device is identical to Predicate Device
	80 @ 10kΩ	80 @ 10kΩ	
Maximum Output Current (mA)	8 @ 500Ω	8 @ 500Ω	Yes

Category	Predicate Device	Subject Device	Substantially Equivalent?
	8 @ 10kΩ	8 @ 10kΩ	Subject Device is identical to Predicate Device
Duration of primary (depolarizing) phase (µsec)	300	300	Yes Subject Device is identical to Predicate Device
Pulse Duration (µsec)	650	650	Yes Subject Device is identical to Predicate Device
Frequency (Hz)	150	150	Yes Subject Device is identical to Predicate Device
Symmetrical phases?	Yes	Yes	Yes Subject Device is identical to Predicate Device
Phase Duration (µS)	300 each phase	300 each phase	Yes Subject Device is identical to Predicate Device
Net Charge (µC)	0 @500Ω	0 @500Ω	Yes Subject Device is identical to Predicate Device
Maximum Phase Charge (µC)	2.4 @ 500Ω	2.4 @ 500Ω	Yes Subject Device is identical to Predicate Device
Maximum Current Density (mA/cm², r.m.s.)	1.29 @ 500Ω	1.29 @ 500Ω	Yes Subject Device is identical to Predicate Device

Category	Predicate Device	Subject Device	Substantially Equivalent?
Maximum Average Current (mA) (average absolute value)	0.72 @ 500Ω	0.72 @ 500Ω	Yes Subject Device is identical to Predicate Device
Maximum Average Power Density (mW/cm²)	2.18 @ 500Ω (0.0022 W/cm^2)	2.18 @ 500Ω (0.0022 W/cm^2)	Yes; Subject Device is identical to Predicate Device
Safety			
Electrical safety	Conforms to IEC 60601 Electrical Safety	Conforms to IEC 60601 Electrical Safety	Yes Subject Device is identical to Predicate Device
Compatibility with intended environments	Conforms to EMC requirements	Conforms to EMC requirements	Yes Subject Device is identical to Predicate Device
Mechanical safety	Conforms to IEC 60601 Electrical Safety	Conforms to IEC 60601 Electrical Safety	Yes Subject Device is identical to Predicate Device
Chemical safety	Not applicable.	Not applicable.	Yes Subject Device is identical to Predicate Device
Thermal safety	Conforms to IEC 60601 Electrical Safety	Conforms to IEC 60601 Electrical Safety	Yes Subject Device is identical to Predicate Device
Radiation safety	Not applicable.	Not applicable.	Yes Subject Device is identical to Predicate Device

VII. PERFORMANCE DATA

The only design difference between the subject device and the predicate device is the formulation of the proprietary electrode material. With the exception of the electrode material, the subject device has identical technological characteristics as the predicate device. All patient-contacting materials were demonstrated to be biocompatible per ISO-10993. No other non-clinical or clinical testing was performed in support of a substantial equivalence determination.

VIII. CONCLUSION

The subject device, Cala kIQ with the new formulation of the electrode material, has the same intended use and indications for use as the predicate device, Cala kIQ (K242259). The subject device has the same control mechanisms, principles of operation, and energy type as the legally marketed predicate device.

The only design difference between the subject device and the predicate device is the formulation of the proprietary electrode material. With the exception of the electrode material, the subject device has identical technological characteristics as the predicate device.

The new formulation of the electrode material and all other patient-contacting materials were tested and demonstrated to be biocompatible per ISO-10993. No other non-clinical or clinical testing was performed in support of a substantial equivalence determination.

The performance data reviewed in previous submissions, including the predicate submission, are still applicable to the subject device since they are similar in technology, and, hence, the previously reviewed data supports that the subject device meets special controls. Therefore, the subject device is substantially equivalent to the predicate device.