March 17, 2026

Cala Health, Inc.
Khushboo Surendran
Senior Regulatory Specialist
1800 Gateway Dr., Suite 120
San Mateo, California 94404

Re: K253587
Trade/Device Name: Cala kIQ Plus
Regulation Number: 21 CFR 882.5897
Regulation Name: External upper limb tremor stimulator
Regulatory Class: Class II
Product Code: QBC
Dated: February 12, 2026
Received: February 12, 2026

Dear Khushboo Surendran:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

XIAORUI TANG -S

For: CDR Jitendra Virani
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.

510(k) Number *(if known)*
K253587

Device Name
Cala kIQ Plus

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

Cala kIQ Plus 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.

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."

K253587
510(k) Summary

I. SUBMITTER

Manufacturer: Cala Health, Inc.
1800 Gateway Drive, Suite 120 San Mateo, CA 94404
Phone: (415) 890-3961
Fax: None

Primary Contact: Khushboo Surendran
Senior Regulatory Specialist, Cala Health, Inc.
khushboo.surendran@calahealth.com
(510) 883-3792

Secondary Contact: Amanda Johnston
Regulatory Counsel for Cala Health, Inc.
ajohnston@gardner.law

(763) 639-6951

Date Prepared: November 17, 2025

II. SUBJECT DEVICE

Trade Name: Cala kIQ™ Plus
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™

Predicate Submission number: K243848

IV. DEVICE DESCRIPTION

Cala kIQ Plus is a small, lightweight, wrist-worn device comprised of three components: a Stimulator, a Band, and a Base Station. Cala kIQ Plus delivers transcutaneous afferent patterned

stimulation (TAPS) to the median and radial nerves of a patient's wrist. The device is operated by a patient at home.

V. INDICATIONS FOR USE

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

Cala kIQ Plus 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 control mechanisms, principles of operation, and energy type as the legally marketed predicate device, Cala kIQ (K243848). The subject device and the predicate device have similar technological characteristics. Both devices use transcutaneous afferent patterned stimulation (TAPS) delivered through electrodes embedded in a wearable band to the median and radial nerves of a patient's wrist. No changes were made to the device hardware. The subject device modification includes updates to the stimulator firmware, user interface and labeling to introduce the optional therapy options feature (Therapy Mode A, Mode B and Mode C) and modifications to existing features such as calibration and stimulation intensity setting, band shelf-life extension, addition of an electronic Instructions for Use and bug fixes proposed in this submission.

Table 1. Cala kIQ Plus Substantial Equivalence

Category	Predicate Device	Subject Device	Substantial Equivalence
510(k) Number	K243848	K253587	-
Manufacturer	Cala Health	Cala Health	-
Device name	Cala kIQ	Cala kIQ Plus	-
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	Identical

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 Plus is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. Cala kIQ Plus 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.	Identical
Target Population	Adults with essential tremor or Parkinson's Disease	Adults with essential tremor or Parkinson's Disease	Identical
Anatomical site	Median and radial nerves	Median and radial nerves	Identical
Intended Users	Adults	Adults	Identical
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.	Identical

Rx or OTC use	Prescription Use only	Prescription Use only	Identical
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	Identical
Energy used or delivered	Electrical stimulation	Electrical stimulation	Identical
Human Factors	Wrist-worn electrical stimulator with detachable wristband containing reusable 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	Identical
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 Plus 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)	Identical
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.	Identical

Electrodes	6 Individual Electrode Surface area 22mm x 6mm = 1.32 cm^2	6 Individual Electrode Surface area 22mm x 6mm = 1.32 cm^2	Identical
Battery and Base Station	Rechargeable Lithium-ion battery and AC-powered charger.	Rechargeable Lithium-ion battery and AC-powered charger.	Identical

Performance			
User Workflow 1: Calibration	Device calibrates once during the initial device setup and can be recalibrated.	Device calibrates at the beginning of every therapy session.	Different. Non-clinical testing and simulated use testing demonstrate that no new question of safety or effectiveness is raised.
User Workflow 2: Stimulation Intensity	Patients set their stimulation intensity during initial setup.	The device will automatically set the stimulation intensity.	Different. Non-clinical testing simulated-use testing demonstrate that no new question of safety or effectiveness is raised.
User Workflow 3: Therapy Options	**Therapy Sessions:** Therapy is available on demand. Therapy session lasts for 40 minutes. Device only provides one Therapy waveform option (Therapy Mode A).	**Therapy Sessions:** Therapy is available on demand. Therapy session lasts for 40 minutes. Device provides Therapy waveform options (Therapy Mode A, Mode B and Mode C).	Different. Non-clinical, simulated-use testing and clinical study demonstrate that no new question of safety or effectiveness is raised.
Treatment Time	40 minutes	40 minutes	Identical
Wristband life	90 days	90 days	Identical

Shelf-life	Cala kIQ Band: 3 months	Cala kIQ Band: 18 months	Different. Extended shelf-life testing demonstrates that no new question of safety or effectiveness is raised.
Output Specifications			
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Identical
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Identical
Maximum Output	4 @ 500Ω	4 @ 500Ω	Identical

Voltage (volts)	80 @ 10kΩ	80 @ 10kΩ	
Maximum Output Current (mA)	8 @ 500Ω	8 @ 500Ω	Identical
	8 @ 10kΩ	8 @ 10kΩ	
Duration of primary (depolarizing) phase (µsec)	300	300	Identical
Pulse Duration (µsec)	650	650	Identical
Frequency (Hz)	150	50- 150	Different. Non-clinical and clinical testing demonstrate that no new question of safety or effectiveness is raised.

Symmetrical phases?	Yes	Yes	Identical
Phase Duration (µS)	300 each phase	300 each phase	Identical
Net Charge (µC)	0 @500Ω	0 @500Ω	Identical
Maximum Phase Charge (µC)	2.4 @ 500Ω	2.4 @ 500Ω	Identical
Maximum Current Density (mA/cm², r.m.s.)	1.29 @ 500Ω	1.29 @ 500Ω	Identical
Maximum Average Current (mA) (average absolute value)	0.72 @ 500Ω	0.72 @ 500Ω	Identical

Maximum Average Power Density (mW/cm²)	2.18 @ 500Ω (0.0022 W/cm^2)	2.18 @ 500Ω (0.0022 W/cm^2)	Identical
Safety			
Electrical safety	Conforms to IEC 60601 Electrical Safety	Conforms to IEC 60601 Electrical Safety	Identical
Compatibility with intended environments	Conforms to EMC requirements	Conforms to EMC requirements	Identical
Mechanical safety	Conforms to IEC 60601 Electrical Safety	Conforms to IEC 60601 Electrical Safety	Identical
Chemical safety	Not applicable.	Not applicable.	Identical
Thermal safety	Conforms to IEC 60601 Electrical Safety	Conforms to IEC 60601 Electrical Safety	Identical
Radiation safety	Not applicable.	Not applicable.	Identical
Cybersecurity	Conforms to FDA cybersecurity requirements	Conforms to FDA cybersecurity requirements	Identical. Software changes concluded to have no impact to cybersecurity testing

VII. PERFORMANCE DATA

The modifications made to the subject device were validated through comprehensive non-clinical and clinical testing to ensure safety and effectiveness.

Non-Clinical Performance Data

Electrical safety and EMC testing was conducted on the subject device per IEC 60601-2-10 standard. The updated software was verified and validated per IEC 62304 and FDA guidance, "*Content of Premarket Submissions for Device Software Functions, June 2023*". Shelf-life testing was conducted to demonstrate the extended 18-month shelf-life of the wristband. The design modification and user interface update made to the subject device has been validated through simulated use testing.

Clinical Performance Data

A clinical study was performed to evaluate the safety and effectiveness of two new therapy modes (Therapy Mode B and Therapy Mode C) compared to Therapy Mode A (standard TAPS therapy) in adults with essential tremor.

Study Design:

The study was a randomized, double-blinded, crossover study involving 30 subjects with essential tremor over a 6-week home-use period. Subjects rotated through three distinct 2-week therapy periods testing each therapy mode (Therapy Mode A, B and C) in a random order with the following stimulation patterns:

1. Therapy Mode A: Standard TAPS
2. Therapy Mode B: TAPS with first new waveform
3. Therapy Mode C: TAPS with second new waveform

Key Eligibility Criteria:

- A diagnosis of essential tremor
- A tremor severity score of 2 or above in the dominant hand/arm as measured by any one of the Tremor Research Group Essential Tremor Assessment (TETRAS) upper limb postural tremor items
- Significant disability due to essential tremor as measured by the Bain & Findley Activities of Daily Living (BF-ADL) score of 3 or above in any one of the upper limb items
- Absence of any other neurodegenerative disease other than essential tremor

Primary Effectiveness Endpoints:

- Tremor power improvement ratio (TPIR):
  - Calculated as the pre-stimulation tremor power divided by the post-stimulation power, which was computed from device-collected accelerometry data.
- In-visit BF-ADL score:
  - Calculated as change in BF-ADL upper limb subset score from pre- to post-stimulation for in-visit therapy sessions

Effectiveness was measured through remote or in-office clinical assessment visits and through retrospective surveys conducted following each 2-week period.

Results:

Patient Population:

Subject demographics included a mean age of 68.1 years (range: 42-83), 53% female and 47% male, mean time from initial diagnosis 22.5 years (range: 5-59), and mean baseline TETRAS score 13.4 (range: 8-19).

Effectiveness:

- All three therapy modes demonstrated improvement in tremor across multiple clinical endpoints, including the two primary endpoints:
    - Tremor power improvement ratio (TPIR) was greater than 1 for all patterns. A TPIR greater than 1 indicates tremor reduction from pre- to post-stimulation. Median TPIR values were 2.13 for Therapy Mode A, 2.86 for Therapy Mode B and 3.71 for Therapy Mode C.
    - In-visit Bain & Findley ADL (BF-ADL) scores from before to after stimulation were improved for all therapy modes. The mean improvement was 3.7 points (Therapy Mode A), 3.5 points (Therapy Mode B) and 4.4 points (Therapy Mode C).
- While there were no population level differences in effectiveness endpoints between the three therapy modes, individual patients did better on their preferred therapy. Preferred therapy mode was identified based on patient-reported satisfaction and comfort ratings. Overall, the preferred therapy mode was Therapy Mode A for 6 subjects (21%), Therapy Mode B for 11 subjects (39%) and Therapy Mode C for 11 subjects (39%).

Safety:

- Eighteen device-related adverse events occurred in thirteen study subjects (46.7% of enrolled subjects)
- All adverse events were mild to moderate, and were predominantly transient sensations such as skin irritation, discomfort and shock, and were consistent with known device risks.
- There were no reports of tissue damage (burns, sores, or lesions) or severe adverse events.
- Only one study subject (3.3%) withdrew from the study due to a moderate adverse event (finger and thumb weakness).
- Incidence of adverse events were similar between therapy modes: Therapy Mode A (13%), Therapy Mode B (20%) and Therapy Mode C (20%).

Summary:

The clinical study demonstrated that patients achieved similar tremor score improvements at the population level across all three Therapy Modes (A, B, and C). Patients had comparable safety profiles across all modes.

VIII. CONCLUSION

The intended use for the subject device and the predicate device is the same. The subject device and the predicate device have similar technological characteristics. The only modifications to the subject device are made on the device firmware, user interface and labeling. There are no changes

made to the device hardware. These modifications have been verified and validated through bench testing, electrical safety testing, and clinical evaluation, demonstrating that there is no new question of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.