October 25, 2018

Cala Health, Inc.
Scott Wilson
Vice President, Regulatory Affairs and Quality Assurance
875 Mahler Road, Suite 168
Burlingame, California 94010

Re: K182706
Trade/Device Name: External upper limb tremor stimulator
Regulation Number: 21 CFR 882.5897
Regulation Name: External upper limb tremor stimulator
Regulatory Class: Class II
Product Code: QBC
Dated: September 25, 2018
Received: September 27, 2018

Dear Scott Wilson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Cala ONE

Indications for Use *(Describe)*

The Cala ONE device is indicated to aid in the transient 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:

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"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:
Special 510(k) for Device Modification

I. Submitter

Cala Health, Inc.
875 Mahler Rd, Suite 168
Burlingame, CA 94010

Official Correspondent:

Scott A. Wilson, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
Cala Health, Inc.

Phone Number:	925.876.5480
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II. Device

Name:	Cala ONE
Classification:	Class II with Special Controls
Regulation name:	External upper limb tremor stimulator
Regulation:	21 CFR 882.5897
Product Code:	QBC

III. Predicate Device

Name:	Cala ONE
Prior submission:	DEN170028

IV. Description of Device and Modification

As described in DEN170028, the Cala ONE is a small, lightweight, wrist-worn stimulator designed to aid in transient essential tremor symptom relief by applying transcutaneous afferent patterned stimulation (TAPS) to the median and radial nerves of a patient's wrist. The Cala ONE device system consists of a charger, the stimulator, and a set of removable electrodes (gels) that work together to transcutaneously deliver electrical stimulation to the nerves.

In configuration cleared under DEN170028, the Cala ONE device includes a set of three single-use hydrogel electrodes. For the convenience of the patient, Cala Health is changing these three single-use electrodes (intended for daily replacement) to three multi-use electrodes (intended for replacement after 30 days). This change is both to the electrode material and to the device labeling. This Premarket Notification has been prepared to address the relevant considerations of FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device," which are:

1. *Regarding the electrode material*, per guidance Section C "Material Changes" this change does not significantly affect the safety or effectiveness of the device. The present Premarket Notification documents the substantial equivalence including electrical safety, energy transfer, biocompatibility, and shelf-life. Specifically, the change does not affect the performance specification, with the exception of the electrode have multi-use durability to 30 days.
2. *Regarding the labeling*, per guidance Section A "Labeling" the change from a device labeled for single use to a device labeled as reusable could affect the safety or effectiveness and would likely require submission of a new 510(k). As noted above, the electrode change does not significantly affect safety or effectiveness of the device and that the minor change in labeling (specifically, to the use instructions in the Patient Guide) is appropriately supported.

V. Indications for Use

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

VI. Summary of Risk Assessment and Design Control Activities

The design control activities associated with development of the multi-use (30 day) electrode included consideration of the relevant special controls established in FDA's letter of April 26, 2018 regarding DEN170028, in particular the assessment of electrical stimulation transfer, biocompatibility, shelf life, and labeling.

The risk assessment activities included analysis of relevant risks identified in FDA's letter of April 26, 2018 regarding DEN170028.

VII. Conclusions

The change being made does not: (1) affect the intended use or (2) alter the fundamental scientific technology of the Cala ONE device.