April 26, 2018

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

Re: DEN170028
Trade/Device Name: Cala ONE
Regulation Number: 21 CFR 882.5897
Regulation Name: External upper limb tremor stimulator
Regulatory Class: Class II
Product Code: QBC
Dated: May 15, 2017
Received: May 17, 2017

Dear Scott Wilson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Cala ONE, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Cala ONE, and substantially equivalent devices of this generic type, into Class II under the generic name external upper limb tremor stimulator.

FDA identifies this generic type of device as:

> **External upper limb tremor stimulator.** An external upper limb tremor stimulator is a prescription device which is placed externally on the upper limb and designed to aid in tremor symptom relief of the upper limb.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request

be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On May 17, 2017, FDA received your De Novo requesting classification of the Cala ONE. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Cala ONE into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Cala ONE can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Tissue damage due to over-stimulation	Non-clinical performance testing Software verification, validation, and hazard analysis Electrical safety testing Shelf life testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Labeling
Electrical shock or burn	Electrical, thermal, and mechanical safety testing Software verification, validation, and hazard analysis Labeling
Interference with other devices	Electromagnetic compatibility (EMC) testing Software verification, validation, and hazard analysis Labeling

In combination with the general controls of the FD&C Act, the external upper limb tremor stimulator is subject to the following special controls:

1. Non-clinical performance testing must assess the following:

    a. Characterization of the electrical stimulation, including the following, must be performed: waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, net charge per pulse, maximum phase charge at 500 ohms, maximum current density, maximum average current, and maximum average power density.

    b. Impedance testing, current distribution across the electrode surface area, adhesive integrity, and shelf life testing of the electrodes and gels must be conducted.

c. Simulated use testing of sensor performance and the associated algorithms that determine the stimulation output must be conducted.

2. Patient-contacting components of the device must be demonstrated to be biocompatible.

3. Performance testing must demonstrate electrical, thermal, and mechanical safety along with electromagnetic compatibility (EMC) of the device in the intended use environment.

4. Software verification, validation and hazard analysis must be performed.

5. Physician and patient labeling must include:

   a. Summaries of electrical stimulation parameters;
   b. Instructions on how to correctly use and maintain the device;
   c. Instructions and explanations of all user-interface components;
   d. Instructions on how to clean the device;
   e. A shelf life for the electrodes and gel; and
   f. Reuse information.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the external upper limb tremor stimulator they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Kristen Bowsher at 301-796-6448.

Sincerely,

Angela C. Krueger -S

Angela C. Krueger
Deputy Director, Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health