11/22/2022

Cala Health, Inc.
Danielle McDonnell Boyd
Senior Director, Regulatory Affairs
1800 Gateway Dr, Suite 300
San Mateo, California 94404

Re: K222237
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: October 21, 2022
Received: October 21, 2022

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,

For: Xiaorui Tang
Date: 2022.11.22 13:34:34 -05'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222237

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.

510(k) Summary

I. SUBMITTER

Manufacturer: Cala Health, Inc.
1800 Gateway Drive, Suite 300 San Mateo, CA 94404
Phone: (415) 890-3961
Fax: None

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

Date Prepared: July 22, 2022

II. SUBJECT DEVICE

Trade Name: Cala kIQ™

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 Trio™

Prior Submissions: DEN170028, K182706, K203288

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.

IV. DEVICE DESCRIPTION

Cala kIQ is a small, lightweight, wrist-worn stimulator device designed to aid in the relief of hand tremors by applying a calibrated Transcutaneous Afferent Patterned Stimulation (TAPS) to the median and radial nerves of a patient's wrist.

The TAPS output pattern is calibrated to the individual patient's tremor frequency. During device setup, the patient performs a postural hold, during which the onboard sensors measure the tremor frequency which is then used to customize the TAPS output pattern to deliver therapy to the median and radial nerves at the appropriate, patient-specific, optimal stimulation frequency.

Cala kIQ is comprised of the following components:

- Stimulator: Contains sensors, electronics, and firmware for delivering TAPS therapy and provides user interface
- Band: Contains multi-use, conductive electrodes spaced at intervals to align with targeted nerves and attachment points for Cala kIQ Stimulator
- Base Station: Provides charging function and contains an indicator light to alert the user to operating conditions.

The Cala kIQ Stimulator contains the electronics, sensors, and firmware for calibrating and delivering TAPS therapy. The patient uses the Cala kIQ Stimulator buttons to complete device calibration, adjust the stimulation amplitude, and initiate therapy sessions. The Cala kIQ Stimulator is attached to the Cala kIQ band, which includes embedded electrodes placed at appropriate intervals 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).

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. SUBSTANTIAL EQUIVALENCE

Table 1 below provides a summary comparison between the Subject Device, Cala kIQ and the Predicate Device, Cala Trio, with respect to intended use, technological characteristics, and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

Table 1. Cala kIQ Substantial Equivalence

	Predicate Device **Cala Trio** **K203288**	**Subject Device** **Cala kIQ** **K222237**	**Substantially Equivalent?**
510(k) Number	K203288	K222237	
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 Trio 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 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 Substantial equivalence demonstrated through clinical evidence
Target Population	Adults with essential tremor	Adults with essential tremor or Parkinson's Disease	Yes Substantial equivalence demonstrated through clinical evidence
Anatomical site	Median and radial nerves	Median and radial nerves	Yes Subject Device is identical to Predicate Device
Intended Users	Patient	Patient	Yes Subject Device is identical to Predicate Device

	Predicate Device Cala Trio K203288	Subject Device Cala kIQ K222237	Substantially Equivalent?
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	Calibrated Transcutaneous Afferent Patterned Stimulation (TAPS) delivered through electrodes embedded on wearable band	Calibrated 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 band containing multi-use electrodes. Base station provides charging function and contains indicator lights for operating status	Wrist-worn electrical stimulator with detachable band containing multi-use electrodes. Base station provides charging function and contains indicator lights for operating status	Yes Subject Device is identical to Predicate Device
Patient Contacting Materials	The following components of the Cala Trio Band have Surface, Intact Skin Long-Term contact (>30 days): • Elastic • Electrodes • Microfiber • Elastic • Band thread	The following components of the Cala kIQ Band have Surface, Intact Skin Long-Term contact (>30 days): • Elastic • Electrodes • Microfiber • Elastic • Band thread	Yes Subject Device is identical to Predicate Device

	Predicate Device **Cala Trio** **K203288**	**Subject Device** **Cala kIQ** **K222237**	**Substantially Equivalent?**
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	1 common, 2 active electrodes Individual Electrode Surface area 22mm x 22mm = 4.84 cm^2)	2 common electrodes paired with 2 active electrodes Individual Electrode Surface area 22mm x 6mm = 1.32 cm^2	Yes Substantial equivalence demonstrated through non- clinical performance testing and clinical evidence
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 2. Set stimulation intensity 3. Therapy available on demand	1. Calibration 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
Wristband life	90 days	90 days	Yes Subject Device is identical to Predicate Device.

	Predicate Device Cala Trio K203288	Subject Device Cala kIQ K222237	Substantially Equivalent?
Shelf-life	Cala Trio Band: 24 months	Cala kIQ Band: 3 months	Yes Shelf-life testing confirms Cala kIQ Band meets product specification at labeled shelf-life. Shelf-life difference from predicate due to availability of test data, not performance characteristics
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 Subject Device is identical to Predicate Device
	8 @ 10kΩ	8 @ 10kΩ	
Duration of primary (depolarizing) phase (µsec)	300	300	Yes Subject Device is identical to Predicate Device

	Predicate Device Cala Trio K203288	Subject Device Cala kIQ K222237	Substantially Equivalent?
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.)	0.50 @ 500Ω	1.29 @ 500Ω	Yes Substantial equivalence demonstrated through non-clinical performance testing and clinical evidence
Maximum Average Current (mA) (average absolute value)	0.72 @ 500Ω	0.72 @ 500Ω	Yes Subject Device is identical to Predicate Device

	Predicate Device Cala Trio K203288	Subject Device Cala kIQ K222237	Substantially Equivalent?
Maximum Average Power Density (mW/cm²)	0.59 @ 500Ω (.0006 W/cm$^{2)}$	2.18 @ 500Ω (0.0022 W/cm^{2})	Yes Substantial equivalence demonstrated through non-clinical performance testing and clinical evidence
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

Non-clinical performance testing confirmed that Cala kIQ complies with performance standards and functions as intended.

Performance testing included bench testing to confirm electrode function, physical characteristics, mechanical function, shelf life, and system performance. Testing confirmed that the Cala kIQ meets the product requirements.

EMC and Electrical Safety testing demonstrated that Cala kIQ is compliant with the applicable IEC 60601 clauses. Biocompatibility evaluations and assessments per FDA Guidance documents demonstrate that Cala kIQ meets the ISO 129993-1:2018 standard and is acceptable for use.

VIII. CLINICAL DATA

Clinical data to support substantial equivalence for the differences in indicated patient populations and technological characteristics includes evidence from two clinical studies.

The first clinical study was a single-arm, non-significant risk study that evaluated calibrated TAPS therapy in patients with Parkinson's Disease who also had postural hand tremor.

A total of forty patients were enrolled in the study. There were no reports of device-related serious adverse events, and all device-related adverse events were resolved with minimal intervention.

Across visits, TAPS therapy improved 0.5±0.5 points on an unvalidated subset of MDS-UPDRS dominant hand tasks listed below:

- Rest Tremor Amplitude
- Postural Tremor
- Kinetic Tremor
- Pronation-Supination
- Finger Tapping
- Hand Movements

Also, across visits, TAPS therapy improved the ability to perform some activities of daily living by 0.4±0.5 points based on an unvalidated subset of BF-ADL tasks listed below:

- Use a spoon to drink soup
- Hold a cup of tea
- Pour milk from a bottle or carton
- Dial a telephone
- Pick up your change in a shop
- Insert an electric plug into a socket
- Unlock your front door with a key
- Write a letter

These results were descriptive in nature, different patients showed improvement in different tasks tested. None of the patients showed improvement in all of the tasks tested and some of the patients showed no improvement in any of the tasks tested.

Pre-stimulation to post-stimulation change was evaluated for each of the MDS-UPDRS Part III dominant hand tasks and the Bain and Findley ADL tasks at both Visits 2 and 3. The MDS-UPDRS and BF-ADL scales are assessed at 1-point increments and improvement was calculated for the average scores as well as for each individual task. The responder rate, defined as the percent of subjects that had a ≥ 0.5-point average per-task improvement, was calculated for the average scores as well as for each individual task. The study design included two visits with study clinicians and a 2-week home use period of during which subjects were instructed to complete TAPS therapy sessions twice daily. Assessment performed during study visits were completed while subjects were off medication, home-use sessions completed with subjects on medication per their standard of care.

Table 2 below provides study data for all enrolled subjects and includes responder rates for assessment averages and individual tasks. Of note, the CGI-I and PGI-I were used as secondary endpoints in the study:

Table 3 below provides the responder rates for study subjects with a score of ≥ 2 for a specific task at the applicable visit. The data in **Table 3** are a subset of the results summarized in **Table 2**.

Table 2. PD-02 Responder Rates for All Enrolled Subjects

	Visit 2					Visit 3				
	N	**Pre** **Mean ± SD**	**Post** **Mean ± SD**	**Change** **Mean ± SD**	**Responder Rate** **(%)**	**N**	**Pre** **Mean ± SD**	**Post** **Mean ± SD**	**Change** **Mean ± SD**	**Responder Rate** **(%)**
	MDS-UPDRS									
Average across 6 tasks*	40	1.63 ± 0.55	1.20 ± 0.69	-0.44 ± 0.44	40%	36	1.51 ± 0.50	1.11 ± 0.57	-0.40 ± 0.37	44%
Rest Tremor	40	1.85 ± 1.10	1.33 ± 1.07	-0.53 ± 0.82	45%	36	1.94 ± 0.95	1.44 ± 1.05	-0.50 ± 0.94	39%
Postural Tremor	40	2.30 ± 0.88	1.35 ± 1.08	-0.95 ± 0.88	70%	36	2.14 ± 0.96	1.31 ± 1.06	-0.83 ± 0.88	61%
Kinetic Tremor	40	1.08 ± 0.92	0.75 ± 0.81	-0.33 ± 0.53	35%	36	1.06 ± 0.92	0.83 ± 0.74	-0.22 ± 0.42	22%
Pronation-Supination	40	1.50 ± 0.91	1.23 ± 0.95	-0.28 ± 0.72	33%	36	1.31 ± 0.95	1.17 ± 1.00	-0.14 ± 0.76	28%
Finger Tapping	40	1.75 ± 0.87	1.45 ± 0.96	-0.30 ± 0.76	28%	36	1.47 ± 0.84	1.03 ± 0.77	-0.44 ± 0.56	42%
Hand Movements	40	1.30 ± 0.82	1.10 ± 0.87	-0.20 ± 0.79	35%	36	1.14 ± 0.80	0.89 ± 0.67	-0.25 ± 0.69	28%

	Visit 2					Visit 3				
	N	**Pre** **Mean ± SD**	**Post** **Mean ± SD**	**Change** **Mean ± SD**	**Responder Rate** **(%)**	**N**	**Pre** **Mean ± SD**	**Post** **Mean ± SD**	**Change** **Mean ± SD**	**Responder Rate** **(%)**
	BF-ADLs									
Average ADL Rating (8 Tasks, 8-32)*	40	1.93 ± 0.50	1.48 ± 0.43	-0.44 ± 0.43	43%	36	1.76 ± 0.48	1.44 ± 0.37	-0.32 ± 0.39	25%
Use a spoon to drink soup	40	2.23 ± 0.97	1.60 ± 0.74	-0.63 ± 0.74	55%	36	2.19 ± 0.92	1.78 ± 0.76	-0.42 ± 0.77	33%
Hold a cup of tea	40	2.13 ± 0.94	1.75 ± 0.84	-0.38 ± 0.84	40%	36	2.03 ± 1.00	1.69 ± 0.79	-0.33 ± 0.68	25%
Pour milk from a bottle or carton	40	2.00 ± 0.72	1.48 ± 0.68	-0.53 ± 0.78	45%	36	1.89 ± 0.67	1.56 ± 0.73	-0.33 ± 0.68	42%
Dial a telephone	40	1.75 ± 0.74	1.23 ± 0.58	-0.53 ± 0.72	45%	36	1.53 ± 0.61	1.17 ± 0.38	-0.36 ± 0.54	33%
Pick up your change in a shop	40	1.60 ± 0.71	1.33 ± 0.53	-0.28 ± 0.64	23%	36	1.42 ± 0.60	1.31 ± 0.52	-0.11 ± 0.52	19%
Insert an electric plug into a socket	**40**	1.65 ± 0.70	1.30 ± 0.52	-0.35 ± 0.70	38%	36	1.42 ± 0.65	1.14 ± 0.42	-0.28 ± 0.61	25%
Unlock your front door with a key	40	1.59 ± 0.72	1.33 ± 0.53	-0.26 ± 0.59	23%	36	1.44 ± 0.61	1.17 ± 0.38	-0.28 ± 0.51	25%

	Visit 2					Visit 3				
	N	**Pre** **Mean ± SD**	**Post** **Mean ± SD**	**Change** **Mean ± SD**	**Responder Rate** **(%)**	**N**	**Pre** **Mean ± SD**	**Post** **Mean ± SD**	**Change** **Mean ± SD**	**Responder Rate** **(%)**
Write a letter	40	2.48 ± 0.78	1.85 ± 0.74	-0.63 ± 0.70	53%	36	2.19 ± 0.86	1.72 ± 0.81	-0.47 ± 0.61	42%
	Global Impression - Improvement									
Clinical Global Impression – Improvement (CGI-I)	40	N/A			78% (31/40)	36	N/A			83% (30/36)
Patient Global Impression – Improvement (PGI-I)	40	N/A			75% (30/40)	36	N/A			81% (29/36)

*For averaged scores, a Responder was defined as subjects that had a ≥ 0.5-point average per-task improvement

Table 3. PD-02 Responder Rates for Subjects with Score ≥ 2 per Task

	Visit 2			Visit 3		
	N	**Change** **Mean ± SD**	**Responder Rate (%)**	**N**	**Change** **Mean ± SD**	**Responder Rate (%)**
MDS-UPDRS						
Action Tremor (Postural and Kinetic)*	18	-0.61 ± 0.58	67%	16	-0.59 ± 0.61	63%
Rest Tremor Amplitude	28	-0.79 ± 0.79	61%	28	-0.57 ± 1.00	39%
Postural Tremor	33	-1.00 ± 0.94	70%	28	-0.93 ± 0.94	64%
Kinetic Tremor	13	-0.54 ± 0.52	54%	12	-0.58 ± 0.51	58%
Pronation-Supination	17	-0.59 ± 0.80	53%	13	-0.23 ± 1.01	38%
Finger Tapping	21	-0.57 ± 0.81	38%	17	-0.65 ± 0.61	59%
Hand Movements	15	-0.47 ± 0.64	40%	10	-0.90 ± 0.74	70%
BF-ADLs						
Use a spoon to drink soup	30	-0.87 ± 0.68	73%	27	-0.56 ± 0.85	44%
Hold a cup of tea	29	-0.59 ± 0.87	55%	23	-0.52 ± 0.79	39%
Pour milk from a bottle or carton	30	-0.73 ± 0.78	60%	26	-0.46 ± 0.76	58%
Dial a telephone	23	-0.91 ± 0.73	78%	17	-0.76 ± 0.56	71%

	Visit 2			Visit 3		
	N	**Change** **Mean ± SD**	**Responder Rate (%)**	**N**	**Change** **Mean ± SD**	**Responder Rate (%)**
Pick up your change in a shop	19	-0.63 ± 0.76	47%	13	-0.54 ± 0.52	54%
Insert an electric plug into a socket	21	-0.81 ± 0.60	71%	12	-0.83 ± 0.83	75%
Unlock your front door with a key	18	-0.61 ± 0.70	50%	14	-0.71 ± 0.61	64%
Write a letter	36	-0.69 ± 0.71	58%	27	-0.63 ± 0.63	56%

*For averaged scores, a Responder was defined as subjects that had a ≥ 0.5-point average per-task improvement

Considering existing data for versions of this device, reviewed and cleared under previous submissions for patients with similar symptoms, this study provides sufficient information to demonstrate that Cala kIQ may be effective 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.

The second study was a prospective, single-center, two-arm, non-significant risk, crossover study demonstrating that Cala kIQ provides TAPS therapy with equivalent safety and effectiveness as compared to Cala Trio.

A total of 19 subjects completed the study, 6 of which had Parkinson's Disease. There were no reports of device-related serious adverse events, and all were resolved with minimal intervention. Clinician-rated tremor assessments (TETRAS and MDS-UPDRS), and subject-rated assessments (BF- ADLs) results were similar for Cala kIQ and Cala Trio.

IX. SUBSTANTIAL EQUIVALENCE

Substantial equivalence of the Subject Device, Cala kIQ, to the Predicate Device, Cala Trio, is demonstrated based on the comparison of labeling, technical characteristics, performance, and both clinical and non-clinical testing.

The intended use is unchanged and the difference in the indications for use has been supported by clinical data as described above.

Performance testing demonstrated that Cala kIQ complies with the same special controls and the same consensus and performance standards as Cala Trio.

X. CONCLUSION

The Subject Device, Cala kIQ, has the same intended use as the Predicate Device, Cala Trio. The differences between the subject and predicate device indications for use do not alter the intended use of the device. Clinical data support the temporary relief of postural and kinetic hand tremor symptoms of some activities of daily living in Parkinson's Disease and demonstrate that Cala kIQ delivers TAPS therapy with equivalent safety and effectiveness as Cala Trio.

The subject and predicate device have similar technological characteristics and the differences do not raise new questions of safety or effectiveness. Performance testing demonstrates that Cala kIQ is as safe, as effective, and performs as well as Cala Trio.

Cala kIQ and Cala Trio are substantially equivalent. Cala Health 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.