February 5, 2026

Encora, Inc.
Allison Davanzo
Vice President, Operations
311 Summer Street
Boston, Massachusetts 02210

Re: K251517
Trade/Device Name: Encora X1™
Regulation Number: 21 CFR 882.5897
Regulation Name: External Upper Limb Tremor Stimulator
Regulatory Class: Class II
Product Code: QBC
Dated: January 5, 2026
Received: January 6, 2026

Dear Allison Davanzo:

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251517

Please provide the device trade name(s).

Encora X1

Please provide your Indications for Use below.

Encora X1 is indicated to aid in the relief of hand tremors in the treated limb during stimulation in adults with essential tremor.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

1. Submitter

Manufacturer: Encora, Inc.
311 Summer Street
Boston, MA 02210
Phone: (855) 699 5313

Primary Contact: Allison Davanzo
Vice President, Operations, Encora
alli@encoratherapeutics.com
Phone: (904) 477 8544

Date Prepared: Jan 2, 2026

2. Subject Device

Trade Name: Encora X1™

Classification Name: External upper limb tremor stimulator

Device Classification: Class II

Regulation: 21 CFR 882.5897

Product Code: QBC

3. Predicate Device

Predicate Device: Cala ONE

Submission Numbers: DEN170028, K182706

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

4. Description of Device

Encora X1™ is a small, wearable stimulator designed to provide essential tremor symptom relief to the treated hand during stimulation. The device is designed to be worn on a patient's wrist and offers two modes of mechanical stimulation ("Continuous" and "Pulsed"). Both stimulation modes are adjusted based on characteristics of a patient's tremor and target the peripheral nerve distributions of the wrist (median, radial, and ulnar). The Encora X1™ system includes three main components: (1) a rechargeable stimulator, (2) a wrist-worn band with linear resonant actuators, and (3) a charging station that recharges the stimulator.

The stimulator component contains the electronics for delivering personalized stimulation to the patient's wrist. There are three buttons on the stimulator that are used to activate and adjust stimulation. The status indicator light on the stimulator provides information on device state, including battery charge, stimulation mode, and other states.

To deliver therapy, the stimulator is attached to the wristband, which includes integrated linear resonant actuators placed at appropriate intervals around the inner diameter of the band to target the appropriate anatomical regions of the wrist. To accommodate a broad range of wrist sizes, the band is available in three sizes (small, medium, and large).

5. Indications for Use

Encora X1™ is indicated to aid in the relief of hand tremors in the treated limb during stimulation in adults with essential tremor.

6. Technological Characteristics

Table 1 provides a summary comparison for technical characteristics between Encora X1™ (subject device) and Cala ONE (predicate device).

Table 1. Technical Comparison of the Subject Device and Predicate Device

	Encora X1™ **K251517** **(Subject Device)**	**Cala ONE** **K182706** **(Predicate Device)**	**Substantially Equivalent?**
510(k) Number	K251517	K182706	
Manufacturer	Encora, Inc.	Cala Health	
Intended Use	Provide tremor symptom relief of the upper limb	Provide tremor symptom relief of the upper limb	Yes

	Encora X1™ **K251517** **(Subject Device)**	**Cala ONE** **K182706** **(Predicate Device)**	**Substantially Equivalent?**
Indications for Use	Encora X1™ is indicated to aid in the relief of hand tremors in the treated limb during stimulation in adults with essential tremor.	Cala ONE is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor.	Yes *The changes in indications for use are supported by clinical evidence.*
Design	Stimulator with on-board motion sensors that is detachable from wristband	Stimulator with on-board motion sensors that is detachable from wristband	Yes *Subject Device is similar to Predicate Device.*
	Wrist-worn band with four linear resonant actuators embedded in the band	Wrist-worn band with three 4.84 cm^2 electrodes embedded in the band	Yes *Substantial equivalence demonstrated through clinical evidence.*
	AC-powered base station for recharging the stimulator	AC-powered base station for recharging the stimulator	Yes *Subject Device is similar to Predicate Device.*
	Embedded firmware control of device calibration, stimulation delivery, and device function	Embedded firmware control of device calibration, stimulation delivery, and device function	Yes *Subject Device is similar to Predicate Device.*
	Device sensors (gyroscope and triaxial accelerometer) measure tremor motion	Device sensors (gyroscope and triaxial accelerometer) measure tremor motion	Yes *Subject Device is similar to Predicate Device.*
Prescription or OTC use	Prescription Use only	Prescription Use only	Yes
Sterility	Non-sterile	Non-sterile	Yes
Battery	Permanent 3.7V Lithium-polymer rechargeable battery	Permanent 3.7V Lithium-ion rechargeable battery	Yes *Substantial equivalence demonstrated through performance and non-clinical testing.*

	Encora X1™ **K251517** **(Subject Device)**	**Cala ONE** **K182706** **(Predicate Device)**	**Substantially Equivalent?**
Frequency of Use	The device is used as needed by the patient.	The device is used as needed by the patient.	Yes *Subject Device is similar to Predicate Device.*
Band Use Life	90 days	90 days	Yes *Subject Device is similar to Predicate Device.*
Weight (g)	Stimulator: 27.5g Band: 30.6g - 33.1g	56g	Yes *The total weight of the patient-worn components of Encora X1™ and Cala ONE (band and stimulator) have equivalent weights.*
Dimensions (mm)	Stimulator: 40 x 47 x 15 Band: 271.0 - 307.1	52 x 79 x 16	Yes *The patient-worn components) of Encora X1™ and Cala ONE (band and stimulator) have equivalent dimensions.*

7. Performance and Non-Clinical Testing

The following tables provide a summary comparison for performance (**Table 2**) and nonclinical testing (**Table 3**) of Encora X1™ (Subject Device) and Cala ONE (Predicate Device).

Table 2. Output Specifications for Encora X1

Stimulation Output Specifications (Encora X1)	
Therapy Session	
Time	30 minutes per day, or as needed
Start/Stop Therapy	Click the Main Button on the center of the face.
Amplitude Increase/Decrease	0.05 Grms per click.

Stimulation Output Specifications (Encora X1)	
Output	
Type	Mechanical Stimulation
Waveform (e.g., pulsed monophasic, biphasic)	Monophasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular
Output Amplitude Range	Min: 0.05 ± 0.002 Grms Max: 0.54 ± 0.12 Grms
Pulse Duration Range	33-167 ms
Duty Cycle	0.5-50%
Carrier Frequency	235±5 Hz
Measurement Accuracy	
Tremor Frequency	±1 Hz in the 3-15 Hz range

Table 3. Nonclinical Testing Comparison of the Subject and Predicate Devices

Output Specification Category	**Encora X1™** **(Subject Device)**	**Cala ONE** **K182706** **(Predicate Device)**	**Comparison Result**
Biocompatibility	Demonstrated Biocompatibility in accordance with ISO 10993-1:2018.	Demonstrated Biocompatibility in accordance with ISO 10993-1:2009.	Equivalent
EMC & Electrical safety	Meets all requirements of IEC60601-1 and relevant collateral and particular standards	Meets all requirements of IEC60601-1 and relevant collateral and particular standards	Equivalent
Stimulation Waveform Testing	Stimulation waveform conforms to requirements of internal standard test method and acceptance criteria	Stimulation waveform conforms to requirements of internal standard test method and acceptance criteria	Equivalent

Output Specification Category	Encora X1™ (Subject Device)	Cala ONE K182706 (Predicate Device)	Comparison Result
Shelf-life testing	Not applicable	Electrode performance conforms to requirements of internal standard test method and acceptance criteria at T=24 months	Not applicable. *The predicate device employed single-use hydrogel electrodes that were supplied within a sealed package. Encora X1™ employs linear resonant actuators which are embedded within the wristband. Testing demonstrated that embedded actuators function as intended for the duration of the 90-day life of the component.*
Software & Cybersecurity	Verification and validation (V&V) testing was conducted, including documentation and hazard analysis, in accordance with FDA Guidance.	Verification and validation (V&V) testing was conducted, including documentation and hazard analysis, in accordance with FDA Guidance.	Equivalent

8. Clinical Testing

Two clinical studies were completed to evaluate the safety and effectiveness of Encora X1 for participants with upper limb tremors caused by essential tremor (ET). The first study was double-blind and sham-controlled, with a randomized crossover design evaluating two active stimulation arms compared to an inactive sham arm (Upper Limb Tremor Reduction in ET (ULTRE) Study, N=43), and the second studied the safety and effectiveness of Encora X1 in a prospectively designed, single-arm confirmatory study with 90 days of follow-up (90-Day Home Use Study consisting of 2 Cohorts (Cohort 1 (N=25 and Cohort 2, N=34)).

8.1.1. Study Design

The ULTRE study was designed as a decentralized, double-blind, sham-controlled, randomized crossover trial. The objective of this study was to demonstrate the safety, tolerability, and efficacy of the Encora device in participants with upper limb tremors caused by essential tremor. Because the study did not pre-specify primary effectiveness endpoints and was not powered for formal hypothesis testing, results are presented descriptively.

Protocol Summary

The ULTRE Study was comprised of the following enrollment phases:

- Screening
- Baseline
- Randomization Treatment Periods

Study participants completed all three Treatment Periods (Continuous stimulation, Pulsed stimulation, Sham stimulation) in accordance with the randomization allocation.

The study was conducted remotely at the patient's own home in order to allow greater geographic enrollment diversity, reduce participant burden, and to reduce the effects of psychosocial environment on tremor severity (i.e., "whitecoat variability").

The study was conducted over 4 to 5 weeks.

Key Eligibility Criteria:

- Age between 22 and 80 years
- A diagnosis of probable or definite ET based on the Tremor Research Investigation Group (TRIG) diagnostic criteria,
- At least one hand exhibiting action tremor ≥ 2 as assessed by the essential tremor Rating Assessment Scale (TETRAS) finger to nose task, duck wing task, OR Archimedes Spiral
- No other possible causes of tremor, including Parkinson's disease, drug-induced tremor, or dystonia

Randomization Inclusion Criteria (additional criteria required prior to randomization):

- During the Baseline evaluation period, a median tremor score of ≥ 2 on at least one hand as assessed by the TETRAS finger to nose task, the duck wing task, OR the Archimedes Spiral, AND
- During the Baseline evaluation period, a median score of ≥ 3 on any one of the subject-assessed items of the Bain & Findley Activities of Daily Living Scale (BF-ADL)

Primary Endpoint

The primary endpoint was the rate of subject-assessed tolerance, on a Subject Tolerability Survey.

Primary Safety Endpoint

The primary safety endpoint was defined as the rate of occurrence of adverse events (AEs).

Key Effectiveness Endpoints

- Bain & Findley Activities of Daily Living (BF-ADL) Composite Score was assessed during stimulation on the final treatment day (Day 3-5) compared to pre-stimulation baseline (Day 1) for each Treatment Period. The BF-ADL Composite Score included 4 tasks:
    - Use a spoon to drink soup
    - Pour milk from a bottle or carton
    - Dial a telephone
    - Insert an electric plug into a socket

- The Essential Tremor Rating Assessment Scale (TETRAS) Composite Score was assessed during stimulation on the final treatment day (Day 3-5) compared to pre-stimulation baseline (Day 1) for each Treatment Period. The TETRAS Composite Score included 5 tasks:
    - Extended Arm
    - Duck Wing
    - Finger-to-Nose
    - Archimedes Spiral
    - Dot Approximation

- Clinical Global Impressions of Change (CGI-C) were assessed at the end of the first Treatment Period only (Day 3-5 Treatment Period 1) to minimize recall bias related to crossover design. The CGI-C is a clinician-rated assessment that reflects the physician's overall impression of the patient's improvement or worsening relative to baseline, measured by a single rating of overall change on a 7-point scale compared to Baseline.

8.1.2. Results

Demographics

Demographics and baseline characteristics were summarized separately for the Safety (N=71) and Effectiveness (N=43) Populations. **Table 4** below provides a summary of the Subject Demographics for these two cohorts.

Table 4. ULTRE Study Demographics for Safety and Effectiveness Populations

Subject Baseline Characteristic	Statistic	Safety Population (N=71)	Effectiveness Population (N=43)
Age, years	median [Q1, Q3]	66 [61, 71]	66 [62, 72]
	mean ± SD	64.3 ± 9.9	65.0 ± 9.6
	(min, max)	(39, 78)	(39, 78)
Age ≥ 65	n/N (%)	42/71 (59.2%)	27/43 (62.8%)
Gender			
Male	n/N (%)	30/71 (42.3%)	19/43 (44.2%)
Female	n/N (%)	41/71 (57.7%)	24/43 (55.8%)
Race			
Black or African American	n/N (%)	2/71 (2.8%)	1/43 (2.3%)
White	n/N (%)	67/71 (94.4%)	41/43 (95.3%)
Asian	n/N (%)	1/71 (1.4%)	0/43 (0.0%)
Not specified	n/N (%)	1/71 (1.4%)	1/43 (2.3%)
Ethnicity			
Not Hispanic or Latino	n/N (%)	70/71 (98.6%)	43/43 (100%)
Essential Tremor (ET) History			
Has family history of ET	n/N (%)	52/71 (73.2%)	32/43 74.4%)
Unknown family history of ET	n/N (%)	7/71 (9.9%)	4/43 (9.3%)
Age of diagnosis	median [Q1, Q3]	46 [36.5, 60]	46 [33, 61]
	mean ± SD	44.7 ± 18.5	44.0 ± 19.0
	(min, max)	(8, 72)	(8, 72)

Tolerability

The stimulation was well-tolerated, with 96% of participants rating the therapy as "comfortable all of the time" across the three stimulation arms (Continuous, Pulsed, and Sham).

Safety

Six device-related adverse events occurred in approximately 7% of participants (5/71, Safety Population) after an average of 24 days of device use. All device-related adverse events were non-serious and self-resolving. See **Table 5** for a summary of device-related adverse events reported in the ULTRE Study.

Table 5. Device-related Adverse Events in ULTRE (Safety Population, N=71)

Description of Event	Relationship to Device	Intensity	Days to Onset
Numbness	Definite	Mild	30
Rash	Definite	Moderate	22
Exacerbation of Pre-existing Carpal Tunnel Syndrome	Probable	Moderate	20
Buzzing	Probable	Mild	29
Numbness & Tingling	Probable	Mild	24
Exacerbation of Pre-existing Psoriasis	Possible	Mild	20

Effectiveness

Both Active stimulations (Continuous and Pulsed) demonstrated improvement in tremor compared to both Baseline and Sham. The effect was observed within approximately 15 minutes of device use and after 3-5 days of treatment. By the end of the Active stimulation Treatment Periods, 70-75% of participants reported at least 1-point improvement in tremor-related disability as measured by the BF-ADL Composite Score, compared to 48% in the Sham arm.

Clinician-assessed global impressions of change (CGI-C) demonstrated that over half of patients in both Active arms (54% Continuous, 63% Pulsed) were rated as improved (defined as minimally improved, much improved, or very much improved on a 7-point scale), compared to only 14% in the Sham group. The CGI-C ratings were limited to the first Treatment Period to minimize recall bias related to crossover design.

Table 6. Summary of ULTRE Study Results (Effectiveness Population, N=43)

	Continuous	Pulsed	Sham
BF-ADL Composite Score (sum of 4 tasks)[a]			
Average Improvement *vs Baseline*	1.48	1.98	0.52
Responder Rate *≥1 point improvement*	75.0% (30/40)	70.0% (28/40)	47.6% (20/42)

	Continuous	Pulsed	Sham
BF-ADL Composite Score (sum of 4 tasks)[a]			
Responder Rate *≥2 points improvement*	37.5% (15/40)	42.5% (17/40)	21.43% (9/42)
TETRAS Composite Score (sum of 5 upper limb tasks)[b]			
Average Improvement *vs Baseline*	0.67	1.45	0.40
Responder Rate *≥1 point improvement*	46.3% (19/41)	60.5% (23/38)	46.3% (19/41)
Responder Rate *≥1.5 points improvement*	31.71% (13/41)	50.0% (19/38)	34.15% (14/41)
Responder Rate *≥2 points improvement*	26.83% (11/41)	39.47% (15/38)	24.39% (10/41)
Global Impressions of Change[c]			
CGI-C Responder Rate	53.8% (7/13)	62.5% (10/16)	14.3% (2/14)

[a] BF-ADL Composite Score comprised 4 tasks (#2 – Use a spoon to drink soup, #4 – Pour milk from a bottle or carton, #17 – Dial a telephone, #21 – Insert an electric plug into a socket). Assessed during stimulation on the final treatment day (Day 3-5) compared to pre-stimulation baseline (Day 1) for each Treatment Period.

[b] TETRAS Composite Score comprised 5 tasks (Extended Arm, Duck Wing, Finger-to-Nose, Archimedes Spiral, Dot Approximation). Assessed during stimulation on the final treatment day (Day 3-5) compared to pre-stimulation baseline (Day 1) for each Treatment Period.

[c] CGI-C comprised a single rating of overall change compared to study Baseline. Assessed by a clinician at end of first Treatment Period only (Period 1, Day 5) to minimize recall bias related to crossover design. Responder=minimally improved, much improved, or very much improved (7-point scale).

Note: *The ULTRE study was designed as a feasibility study without pre-specified primary effectiveness endpoints or formal hypothesis testing. Results are presented descriptively.*

8.2. 90-Day Home Use Study

8.2.1. Study Design

The 90-Day Home Use Study was a prospective single-arm, open-label study consisting of seven remote visits over a 90-day home-use period. Participants were instructed to use the device for a minimum of 30 minutes per day for at least 5 days per week between visits. At each remote visit, participants performed diagnostic movements with and without stimulation to gather data on their response, and used the device on their own between visits.

The study enrolled 60 participants in two sequential cohorts. Cohort 1 (N=25) was used to generate hypotheses and Cohort 2 (N=34) was prospectively designed and used to confirm study outcomes. While subjects were not blinded, the raters assessing effectiveness endpoints were blinded for all tasks.

Key Eligibility Criteria

- A diagnosis of essential tremor defined as definite or probable ET based on the TRIG diagnostic criteria
- At least one hand exhibiting tremor ≥ 2 as assessed by the TETRAS finger to nose task, duck wing task, OR Archimedes Spiral completed during the Screening visit
- At the Screening Visit, a score of ≥ 3 on one of the following subject-assessed items of the BF-ADL scale:
    - Use a spoon to drink soup
    - Hold a cup of tea
    - Do up buttons
    - Do up a zipper
    - Write a letter

8.2.2. Results

Demographics

Demographic characteristics were summarized separately for the Safety (N=60) and Effectiveness Populations (N=59), including Cohort 1 and Cohort 2.Continuous variables (e.g., age) are presented as mean ± SD (plus median and range, where appropriate), and categorical variables (e.g., sex, race) are provided as n/N (%). **Table 7** presents the demographics and baseline characteristics.

Table 7. Demographics and Baseline Characteristics for Safety and Effectiveness Populations (Cohorts 1 and 2)

Subject Baseline Characteristic	Statistic	Safety Population (N=60)	Effectiveness Population (N=59)
Age, years	median [Q1, Q3]	72.0 [66.0, 76.0]	72.0 [66.0, 76.0]
	mean ± SD	69.6 ± 11.2	69.4 ± 11.2
	(min, max)	(28, 93)	(28, 93)
Age ≥ 65	n/N (%)	49/60 (80.0%)	48/59 (80.0%)
Gender			
Male	n/N (%)	31/60 (51.7%)	31/59 (52.5%)
Female	n/N (%)	29/60 (48.3%)	28/59 (47.5%)

Subject Baseline Characteristic	Statistic	Safety Population (N=60)	Effectiveness Population (N=59)
Race			
Black or African American	n/N (%)	0/60 (0.0%)	0/59 (0.0%)
White	n/N (%)	57/60 (95.0%)	56/59 (94.9%)
Asian	n/N (%)	1/60 (1.7%)	1/59 (1.7%)
Native Hawaiian or Other Pacific Islander	n/N (%)	1/60 (1.7%)	1/59 (1.7%)
Not specified	n/N (%)	1/60 (1.7%)	1/59 (1.7%)
Ethnicity			
Not Hispanic or Latino	n/N (%)	57/60 (95.0%)	57/59 (96.6%)
Hispanic or Latino	n/N (%)	2/60 (3.3%)	1/59 (1.7%)
Not specified	n/N (%)	1/60 (1.7%)	1/59 (1.7%)
Essential Tremor History			
Has family history of ET	n/N (%)	48/60 (80.0%)	47/59 (79.7%)
No family history of ET	n/N (%)	12/60 (20.0%)	12/59 (20.0%)
Age of diagnosis	N	59	58
	median [Q1, Q3]	52.0 [33.5, 63.0]	52.0 [36.25, 63.0]
	mean ± SD	47.6 ± 18.9	48.3 ± 18.3
	(min, max)	(8, 79)	(8, 79)
Age of diagnosis ≥ 45	n/N (%)	37/60 (61.7%)	37/59 (62.7%)

Safety

Ten device-related adverse events occurred in approximately 12% of participants (7/60, Safety Population) after an average of 21 days of device use. All device-related adverse events were non-serious and self-resolving. See **Table 8** for a summary of device-related adverse events reported in the 90-Day Home Use Study.

Table 8. Device-related Adverse Events in the 90-Day Home Use Study (Safety Population, N=60)

Description of Event	Relationship to Device	Intensity	Days to Onset
Acute Paresthesia	Definite	Mild	4
Muscle Weakness	Definite	Mild	7
Arthralgia	Definite	Moderate	14
Numbness in Fingers	Probable	Mild	64
Numbness	Probable	Moderate	7
Tingling in Arm	Probable	Moderate	38

Description of Event	Relationship to Device	Intensity	Days to Onset
Pain/Discomfort	Probable	Moderate	35
Worsening of Essential Tremor	Possible	Moderate	29
Vertigo	Possible	Mild	0
Irritability	Possible	Moderate	7

Effectiveness

Analysis of Cohort 1 demonstrated consistent improvement across BF-ADL and TETRAS scores on Days 0 and 90, as well as in Patient Global Impression of Severity (PGI-S) at Day 90. The findings were used to prospectively design Cohort 2 analyses.

The prospectively designed Cohort 2 demonstrated improvement in the 11-task BF-ADL Composite score at Day 90 and in Patient Global Impression of Severity (PGI-S) at Day 90. Improvements were also observed in BF-ADL at Day 0 and clinician-rated TETRAS Composite scores at Day 0 and Day 90.

Table 9. Summary of 90-Day Home Use Study Results (Effectiveness Population N=59)

Analysis		Cohort 1 (N=25)[d] Improvement (ls-mean ± SE)	Cohort 2 (N=34) Improvement (ls-mean ± SE)	Pooled Cohort (N=59)[d] Improvement (ls-mean ± SE)
Primary Endpoint	**BF-ADL[a] Day 90**	4.60 ± 0.88	3.24 ± 0.59	3.80 ± 0.52
Secondary Endpoints	**PGI-S[b] Day 90**	0.76 ± 0.17	0.47 ± 0.12	0.58 ± 0.10
	BF-ADL[a] Day 0	2.56 ± 0.88	2.85 ± 0.59	2.72 ± 0.52
	TETRAS[c] Day 0	0.62 ± 0.25	0.35 ± 0.24	0.47 ± 0.17
	TETRAS[c] Day 90	0.64 ± 0.25	0.63 ± 0.24	0.63 ± 0.17

[a] BF-ADL Composite Score: 11 tasks assessing activities of daily living (#2 – Use a spoon to drink soup, #3 – Hold a cup of tea, #4 – Pour milk from a bottle or carton, #12 – Do up buttons, #13 – Do up a zip, #14 – Write a letter, #15 – Put a letter in an envelope, #16 – Hold and read a newspaper, #17 – Dial a telephone, #20 – Pick up your change in a shop, #21 – Insert an electric plug into a socket).

[b] PGI-S: Single-item patient rating of tremor severity over past week (7-point scale: 1=not present, 7=extremely severe).

[c] TETRAS Composite Score: 5 upper limb tremor tasks (Extended Arm, Duck Wing, Finger-to-Nose, Archimedes Spiral, Dot Approximation).

[d] Analyses showed consistency of treatment effects, but were not prospectively defined.

Improvement calculations:

- The least squares mean (ls-mean) provides model-adjusted estimates of mean change that appropriately accounts for repeated measures, baseline adjustment, missing data, and disease variability.
- Day 90: Change from pre-stimulation baseline at Day 0 to Day 90 during stimulation.
- Day 0: Change from pre-stimulation baseline at Day 0 to during stimulation at Day 0.

By Day 90, 80% of Cohort 1 participants demonstrated at least a 1-point improvement in the BF-ADL Composite score, and 76% demonstrated at least a 2-point improvement. In Cohort 2, 77% of participants demonstrated at least 1 point of improvement in the BF-ADL Composite score, and 71% demonstrated at least 2 points of improvement.

The increased duration of evaluation at 90 days further confirms that Encora X1™ provides consistent, tremor relief and reliable functional improvements that continue with 90 days of use.

8.3. Summary

Collectively, data obtained from the ULTRE RCT and the 90-Day Home Use Study supports that the safety and performance profile of Encora X1 is substantially equivalent to the predicate device.

9. Substantial Equivalence Conclusions

Encora X1™ and Cala ONE are substantially equivalent external upper limb tremor stimulators. Encora has provided evidence to demonstrate that any differences in indications for use and technological characteristics do not impact the substantial equivalence to the predicate device in terms of safety and effectiveness.