June 16, 2021

EnsoData, Inc.
Sigrid Schoepel
Director of Regulatory Affairs
111 S. Hamilton St. Suite 30
Madison, Wisconsin 53703

Re: K210034
Trade/Device Name: EnsoSleep
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: May 11, 2021
Received: May 12, 2021

Dear Sigrid Schoepel:

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,

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic 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)*
K210034

Device Name
EnsoSleep

Indications for Use *(Describe)*
EnsoSleep is intended for use in the diagnostic evaluation by a physician to assess sleep quality and as an aid for physicians in the diagnosis of sleep disorders and respiratory related sleep disorders in pediatric and adult patients as follows:

- Pediatric patients 13 years and older with polysomnography (PSG) tests obtained in a Hospital or Sleep Clinic
- Adult patients with PSGs obtained in a Hospital or Sleep Clinic
- Adult patients with Home Sleep Tests

EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas (OSA), central sleep apneas (CSA), and hypopneas.

All automatically scored events and physiological signals which are retrieved, analyzed, displayed, and summarized are subject to verification by a qualified clinician. Central sleep apneas (CSA) should be manually reviewed and modified as appropriate by a clinician.

All events can be manually marked or edited within records during review.

Photoplethysmography (PPG) total sleep time is not intended for use when electroencephalograph (EEG) data is recorded. PPG total sleep time is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

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.

K210034 EnsoSleep
Traditional 510(k) Summary
Prepared in accordance with the content and format outlined in 21 CFR 807.92

I. SUBMITTER INFORMATION

Name: EnsoData, Inc.
Address: 111 S. Hamilton Street, Suite 30
Madison, WI 53703 USA
Phone: (608)509-4704

Contact Person: Sigrid Schoepel
Email: sigrid@ensodata.com

Date: June 8, 2021

II. SUBJECT DEVICE INFORMATION

Trade Name: EnsoSleep
Common Name: Automatic Event Detection Software for Polysomnography with Electroencephalograph (EEG)
Classification Name: Electroencephalograph 21 CFR 882.1400
Regulatory Class: II
Product Code: OLZ
Intended Use:

EnsoSleep is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep disorders and respiratory related sleep disorders in pediatric patients ages 13 years and older. EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas, central apneas, and hypopneas. All automatically scored events and physiological signals analyzed are retrieved, displayed, and summarized, and are subject to verification by a qualified clinician. All events can be manually marked or edited within records during review.

Target
Patient Population: Adult and Pediatric

III. PREDICATE DEVICE

K162627
Trade Name: EnsoSleep
Target Patient Population: Adults only

IV. SUBJECT DEVICE DESCRIPTION

EnsoSleep is a software-only medical device that analyzes previously recorded physiological signals obtained during sleep. Users of EnsoSleep are consistent with the roles required to run a sleep clinic: sleep physicians, sleep technicians, clinic operations managers, and IT administrators. EnsoSleep can analyze at-home and in-lab sleep studies for both adult and pediatric patients who are at least 13 years old. Automated algorithms are applied to the raw signals in order to derive additional signals and interpret the raw and derived signal information. The software automates recognition of the following: respiratory events, sleep staging events, arousal events, movement events, cardiac events, derived signals, and calculated indices. EnsoSleep does not interpret the results, nor does it suggest a diagnosis. The device only marks events of interest for review by a physician who is responsible for diagnoses. The device does not analyze data that are different from those analyzed by human scorers.

The signals and automated analyses can be visually inspected and edited prior to the results being integrated into a sleep study report.
The software consists of 4 major components:

- The Application Platform runs on local clinic workstations and manages the detection, upload, and download of study records and scoring to and from the Storage Platform
- The Processing Platform accepts raw physiological signals as inputs in order to recognize events, derive signals, and calculate indices
- The Storage Platform facilitates file and database storage in the EnsoSleep cloud through an API
- The Dashboard is a web-based user interface to support configuration, clinic management, and sleep study scoring

<u>Input signals used to derive outputs include</u>:

- Electroencephalogram (EEG)
- Electrocardiogram (ECG)
- Electro-oculogram (EOG)
- Electromyogram (EMG)
- Actigraphy
- Airflow
- Oximetry
- Saturation of Peripheral Oxygen (SpO2)
- Respiratory Inductance Plethysmogram (RIP)
- Polyvinylidene Flouride (PVDF)
- Photoplethysmogram (PPG)
- Pulse Rate
- Snoring Microphone
- Esophogeal Manometry

<u>Outputs that are displayed to users include</u>:

- Respiratory Events
    - Obstructive Sleep Apneas (OSA)

    - Central Sleep Apneas (CSA)
    - Mixed Sleep Apneas (MSA)
    - Hypopneas
    - Cheyne-Stokes Respiration
    - Periodic Breathing
- Sleep Staging Events
    - Stage Wake
    - Stage N1
    - Stage N2
    - Stage N3
    - Stage REM (rapid eye movement)
- Arousal Events
    - Arousals
- Movement Events
    - Leg Movements (LM)
    - Periodic Leg Movement Series (PLMS)
- Cardiac Events*
    - Bradycardia
    - Tachycardia
- Respiratory Rate Events
    - Respiratory Rate
- Sleep-Wake Events
    - Wake
    - Sleep
- Apnea-Hypopnea Index (AHI)
- Sleep Architecture
- Sleep Efficiency (SE)
- Arousal Index (ArI)
- Sleep Latency (SL)
- REM Latency (RL)
- Total Sleep Time (TST)
- Periodic Leg Movements (PLMS) Index

Capnogram data are not displayed to users.

<u>The primary differences between the predicate device and subject device include</u>:
-Target patient population: pediatric patients are included
-Automated scoring of Cheyne-Stokes and Periodic Breathing respiration events and Total Sleep Time
-Browser-based scoring interface to view and edit sleep studies
-Home-sleep studies are supported

** The tachycardia and bradycardia outputs are not for use for cardiovascular monitoring or diagnosis, nor does the device detect arrhythmias.*

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the predicate device EnsoSleep with the subject device EnsoSleep.

Element	Predicate Device EnsoData, Inc. K162627 EnsoSleep	Submitted Device EnsoData, Inc. K210034 EnsoSleep	Discussion
Indications for use	EnsoSleep is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory related sleep disorders in adults only. EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas. All automatically scored events are subject to verification by a qualified clinician. Central apneas, mixed apneas, and hypopneas must be manually marked within records.	EnsoSleep is intended for use in the diagnostic evaluation by a physician to assess sleep quality and as an aid for physicians in the diagnosis of sleep disorders and respiratory related sleep disorders in pediatric and adult patients as follows: • Pediatric patients ages 13 years and older with polysomnography (PSG) tests obtained in a Hospital or Sleep Clinic • Adult patients with PSGs obtained in a Hospital or Sleep Clinic • Adult patients with Home Sleep Tests EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas (OSA), central sleep apneas (CSA), and hypopneas. Central sleep apneas (CSA) should be manually reviewed and modified as appropriate by a clinician.	Different The subject device includes expansion of the indications for use to the pediatric population. Clinical testing using the scoring methodology for the predicate device were applied and validation to demonstrate scoring for expanded uses to pediatric population and new automated outputs.

Element	Predicate Device EnsoData, Inc. K162627 EnsoSleep	Submitted Device EnsoData, Inc. K210034 EnsoSleep	Discussion
		All events can be manually marked or edited within records during review. Photoplethysmography (PPG) total sleep time is not intended for use when electroencephalograph (EEG) data is recorded. PPG total sleep time is not intended to be used as the sole or primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.	
Intended Use	Analyze pre-recorded physiological data acquired during sleep.	Same as predicate.	Same
Patient population	Adults only.	Adults and pediatric patients 13 years old and above.	Different
Environment of use	Physician office (data analysis and reporting). No limitation on where data are acquired.	Same as predicate.	Different; the subject device includes analysis of home sleep testing (HST) of adult patients.
Signals analyzed	EEG, ECG, EOG, EMG waveforms; SpO2; respiratory effort; airflow; heart/pulse rate; snoring loudness; head movement and position.	EEG, ECG, EOG, EMG waveforms; SpO2; respiratory effort; airflow; heart/pulse rate; snoring loudness; head movement and position.	Similar
Sleep measures	Sleep, REM and N3 onset; total sleep and recording times; sleep efficiency % time by sleep stage; awakenings per hour; wake after sleep onset.	Same as predicate.	Same
Automatically score sleep stages	Yes; automatically detects stage Wake (W), REM (R),	Same as predicate.	Same

Element	Predicate Device EnsoData, Inc. K162627 EnsoSleep	Submitted Device EnsoData, Inc. K210034 EnsoSleep	Discussion
	NREM 1 (N1), NREM 2 (N2) and slow wave sleep (N3).		
Automatically score sleep disordered breathing events	No; OSA, CSA and mixed hypopneas must be manually scored	Yes; automatic detection of the following events: • Obstructive apneas (OSA), Central apneas (CSA), • Hypopneas, • Cheyne-Stokes respiration (CSR), and • Periodic breathing (PBE). • Additional apnea and sleep disordered breathing event types may be manually marked within the records. CSA events should also be manually scored	Similar Sleep disordered breathing events are detected, and the additional events are identified using the existing airflow inputs as in the predicate device.
Automatically score arousal events	Yes; automatically detects arousal events.	Yes; automatically detects arousal events; respiratory-effort related arousals, limb movement related arousals, and spontaneous cortical arousal.	Different The general arousal events detected by the subject device are now identified more specifically as to the type of arousal events (same events as detected by the predicate).
Automatically score movement events	Yes; automatically detects leg movement events.	Same as predicate.	Same
Automatically score cardiac events	No.	Yes; brachycardia and tachycardia.	Different The ECG signals used to determine these events were used in the predicate device to determine breathing, arousal, and movement events are also used to detect cardiac events. The tachycardia and bradycardia feature is not intended for use for cardiovascular monitoring or diagnosis, nor does the

Element	Predicate Device EnsoData, Inc. K162627 EnsoSleep	Submitted Device EnsoData, Inc. K210034 EnsoSleep	Discussion
			subject device detect arrhythmias.
Automatically determine derived values	No.	Yes; effort belt respiratory rate and PPG respiratory rate.	Different The RIP and PVDF signals used to determine these values are used in the predicate device to determine breathing, arousal, and movement events.
Automated study upload and download	Yes.	Same as predicate.	Same
Automatically initiates study scoring	Yes.	Same as predicate.	Same
Heart rate accuracy	No.	Same as predicate.	Same
Head position	No.	Same as predicate.	Same
Snoring level	No.	Same as predicate.	Same
Allows editing in sleep study viewers	Yes. Sleep studies can be opened and edited in sleep study scoring devices that support EDF formatted files.	Yes, and within EnsoSleep using EDF formatted files.	Different The subject device allows that signals be edited within the existing patient view of the web dashboard.
Sleep study reporting	Yes.	Same as predicate.	Same
Two-night reports	No.	Same as predicate.	Same
Disease management comments	No.	Same as predicate.	Same
Data format	EDF	Same as predicate.	Same
Compatibility	Operates on any PC with Windows 7 and 8 operating system platforms.	Operates on any PC with Windows 7+, Windows Server 2012+ operating system platforms.	Updated; Tested on newer versions of Windows as they are released, using the

Element	Predicate Device EnsoData, Inc. K162627 EnsoSleep	Submitted Device EnsoData, Inc. K210034 EnsoSleep	Discussion
			same verification methodology.
Cybersecurity	Authentication controls, authorization controls, cryptographic controls, access controls, checksum controls, software distribution controls, intrusion detection system controls, network and systems controls, and database controls.	Same as predicate.	Same
Network requirements	High-speed internet connection, above 200 kb/s recommended.	Same as predicate.	Same

VI. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination. Since this is a software-only medical device that does not control other devices the performance data do not include biocompatibility, electrical safety, electromagnetic compatibility, mechanical, acoustic, or animal testing.

The intended use population, study population, conditions of interest, designated comparative reference, designated comparative benchmarks, and experimental endpoints were defined. Following the application of clinical laboratory selection controls, five (5) clinical testing laboratories were evaluated, and two (2) AASM Accredited Sleep Testing Facilities were selected each with two (2) regional sleep testing centers that met all laboratory quality, external validity, and subject spectrum controls. Following a cross-sectional study design, an archived collection of retrospective diagnostic clinical PSG subject data was collected and verified to meet the specified disease spectrum, medical condition, medication, and demographic requirements. To construct the final study sample from the archived collection population, a randomized sampling with proportionate allocation across each sleep apnea disease severity quantile (normative, mild, moderate, and severe sleep apnea) was used to construct a valid Adult Sample of N=100 adult subjects (AHI mean: 22.4 [95% CI: 18.6%, 26.1%], std: 18.8, median: 17.2, min: 0, max: 109.2, rule: 1.a.) and Pediatric Sample of N=47 pediatric subjects (AHI mean: 11.4 [95% CI: 7.6%, 15.6%], std: 13.6, median: 7.0, min: 0, max: 60.3, rule: 1.a.) from the first laboratory N=1984 archived collection of retrospective diagnostic clinical PSG data, and a valid Respiratory Rate Sample of N=100 adult subjects (AHI mean: 13.2 [95% CI: 9.7%, 16.5%], std: 17.1, median: 6.6, min: 0, max: 82.9, rule: 1.b.) from the second laboratory N=1079 archived collection of retrospective diagnostic clinical PSG data.

The N=100 Adult, N=47 Pediatric, and N=100 Respiratory Rate Study Samples were observed and verified to have no statistically significant differences in the sleep apnea disease state distributional characteristics relative to the laboratory archived collection populations, confirming preservation of disease spectrum breadth and representativeness with respect to the intended use population. The N=100 study samples were verified to contain subjects from all (4/4) sleep apnea disease state severity quantiles, including normative, mild, moderate, and severe sleep apnea, subjects from all (7/7) of the predetermined relevant and/or confounding medical condition groups of interest, including sleep disorders, psychiatric disorders, neurologic disorders, neuro-developmental disorders, cardiac disorders, pulmonary disorders, metabolic and other disorders, subjects from all (5/5) predetermined relevant and/or confounding medication groups of interest, including benzodiazepines, antidepressants, stimulants, opiates, and sleep aids, subjects from each of (7/7) identified demographic group of interest, including all sexes, adult age groups, pediatric age groups, BMI groups, weight groups, height groups, and sleepiness groups. Based on these verification and control procedures, the study sample was determined to be a representative sample of the defined intended use and user population.
Following the finalization of each N=100 subject Adult, N=47 Pediatric, and N=100 Respiratory Rate study sample respectively, six (6) clinical testing laboratories were evaluated for independent manual scoring, three (3) laboratories were selected, and the clinical test setting was established for constructing a valid 2/3 Majority Scoring consensus reference, using N=9 total registered scoring technologists (RPSGTs) with 5 to 20+ years clinical experience by verification

of meeting all defined study scoring-acquisition, scoring-blind, and rater-quality certification controls. Manual scoring for sleep stage, hypopnea events, obstructive sleep apnea (OSA) events, central sleep apnea (CSA) events, arousal events, limb movement events, respiratory effort related arousal (RERA) events, cheyne-stokes (CS) respiration events, and periodic breathing (PB) events were prospectively collected from three (3) independent, registered sleep technologists (RPSGT) for the N=100 Adult and N=47 Pediatric subjects, and manual scoring for sleep stage and respiratory rate events for the N=100 Respiratory Rate subjects, selected as the study population sample, by randomized, double-blinded assignment of each subject to three (3) additional, prospective scorers from the panel of N=9 total independent registered sleep technologists. The designated comparative reference was constructed using 2/3 Majority Scoring to evaluate the subject EnsoSleep device performance versus the predicate EnsoSleep device (K162627) performance for all event types and experimental endpoints evaluated, and the reference device Michele Sleep Scoring device (K112102) performance for hypopnea and central sleep apnea event types specifically. Objective performance benchmarks and acceptance criteria in terms of positive agreement (PA), negative agreement (NA), overall agreement (OA), mean absolute error (MAE), Deming Regression analysis slope and intercept coefficients, Bland-Altman mean difference and 95% upper and lower limits of agreement, each with 95% two-sided bootstrap confidence intervals (R=2000), were predefined competitively based on analysis of reported performance in the predicate device 510(k) event detection and diagnostic agreements reported. In particular, the acceptance criteria were selected based on PA, NA, OA, MAE, Deming Regression coefficient, Bland-Altman mean difference and limits of agreement performance criteria that validate performance substantially equivalent to, or greater than, but not lesser than by more than 10% or similarly defined criteria in any category of the predicate 510(k) reported device performance across all endpoints respectively.

Clinical validation testing performance analysis was collected with the final EnsoSleep software release version, final revision level, final design specification, final instructions for use, and indications for use, in the intended use environment, on the intended use population, and by the intended users, in order to validate the substantial equivalence, and the safety and effectiveness of the subject EnsoSleep device for its intended use. EnsoSleep device performance was evaluated using the defined cross-sectional experimental design, statistical methodology, and set of comprehensive experimental controls, across the following four (4) experimental endpoints:

1. EnsoSleep is intended to assist clinicians with the assessment of sleep quality, therefore performance of device sleep scoring must be validated.
2. EnsoSleep is intended to assist clinicians with the scoring sleep disordered breathing events used in diagnostic evaluation, therefore device performance for diagnosing sleep apnea must be validated.
3. EnsoSleep is intended to analyze physiological signals and automatically score sleep study results, including detection of SDB events, Hypopnea events, Apnea events, including OSA events, CSA events, Arousal events, Limb Movement events, RERA events, CS events, and PB events, therefore device performance for detecting each event type must be validated.
4. EnsoSleep is intended to analyze physiological signals and automatically score sleep study results, including detection of Respiratory Rate events, Sleep-Wake events, and Total Sleep Time, therefore device performance for detecting each event type must be validated.

The final experimental results and statistical analysis were reported for each endpoint. In total PA, NA, OA, Kappa and two-sided 95% bootstrap median confidence intervals (R=2000) were calculated by pooled-epochs versus 2/3 Majority Scoring in 20 event detection experiments evaluating 6 sleep staging events (Wake, N1, N2, N3, REM, Total) in 3 samples (adult, pediatric, and RR), 11 scoring events (SDB, HYP 1.a. (3%), HYP 1.b. (4%), Apnea, OSA, CSA, Arousal, Limb Movement, RERA, CSE, PBE) in 2 samples (adult and pediatric), and 3 physiologic analysis events (RR, Sleep-Wake, TST) with PA, NA, OA, Kappa, Deming Regression $\beta 1$ slope and $\beta 0$ intercept regression coefficients, and Bland-Altman analysis, including mean differences (MD), upper limits of agreement (ULOA), and lower limits of agreement (ULOA) with two-sided 95% bootstrap confidence intervals for Sleep-Wake, TST in 3 samples (adult, pediatric, and RR) as well as mean absolute error (MAE) and percent epochs ±2 breaths per minute for respiratory rate (RR) scoring in the RR adult sample, and 6 sleep apnea diagnostic severity categories (AHI ≥ 5, AHI ≥ 15, REM-AHI ≥ 15, REM-AHI ≥ 15, subgroup AHI ≥ 1, subgroup AHI ≥ 10) in 2 samples (adult and pediatric) with PA, NA, OA, Kappa, two-sided 95% bootstrap median confidence intervals (R=2000), and positive and negative likelihood ratio pairs, across all 4 experimental endpoints respectively.

The subject EnsoSleep device event detection and diagnostic agreement performance were observed to meet or exceed the PA, NA, and OA performance acceptance in the 26 total experiments (26/26) across all 4 experimental endpoints evaluated, including all 20 event detection experiments (20/20) and all 6 diagnostic agreement experiments (6/6), and with all 4 experimental endpoints (4/4) statistically analyzed and evaluated in two or more samples (≥2) per each endpoint respectively (2/2 Adults and Pediatrics in Endpoints 2 and 3, and 3/3 Adults, Pediatrics, and RR in Endpoints 1 and 4):

- For sleep staging events Endpoint 1, all 3 EnsoSleep PA, NA, and OA point-estimates vs 2/3 Majority Scoring were observed to be greater than the predicate device PA, NA, and OA point-estimates vs 2/3 Majority Scoring in some events in the Adult Sample (Wake, N2, REM, Total), Pediatric Sample (Wake, N1, N2, N3, REM, Total,), and RR Sample (Wake, N2, N3, REM, Total). Additionally, some of those event detection differences that were in all 3 performance categories (PA/NA/OA) represented a statistically significant result in terms of higher agreement with 2/3 Majority Scoring, based on low/upper-bound comparison of two-sided 95% bootstrap percentile method confidence intervals to the predicate performance, in each sample: Adult Sample (REM), Pediatric Sample (Wake, N3, Total), and RR Sample (Wake, N2, REM, Total). None of the 6 events evaluated were observed with PA, NA, or OA point-estimates vs 2/3 Majority Scoring that were 10% or lower in any of the sleep staging event types evaluated.
- For sleep apnea diagnostic agreement Endpoint 2, all 3 EnsoSleep PA, NA, and OA point-estimates vs 2/3 Majority Scoring were observed to be greater than the predicate device PA, NA, and OA point-estimates vs 2/3 Majority Scoring in some OSA severity categories in the Adult Sample (AHI ≥ 5) and Pediatric Sample (AHI ≥ 1). There were no samples or OSA severities for which there were statistically significant differences observed in all 3 performance measures (PA/NA/OA), based on low/upper-bound comparison of two-sided 95% bootstrap percentile method confidence intervals. With the exception of Pediatric Sample AHI ≥ 10 PA with an observed comparison of 12.6%, none of the 6 OSA severity categories evaluated were observed with PA, NA, or OA point-

estimates vs 2/3 Majority Scoring that were 10% or lower in any of the 3 diagnostic agreement performance criteria evaluated (PA/NA/OA) respectively.

- For scoring events Endpoint 3, all 3 EnsoSleep PA, NA, and OA point-estimates vs 2/3 Majority Scoring were observed to be greater than the designated predicate device PA, NA, and OA point-estimates vs 2/3 Majority Scoring in some events in the Adult Sample (SDB, HYP, OSA, CSA, Arousal) and the Pediatric Sample (SDB, HYP, CSA, Arousal, RERA). Additionally, some of those event detection differences that were in all 3 performance categories (PA/NA/OA) represented a statistically significant result, based on low/upper-bound comparison of two-sided 95% bootstrap percentile method confidence intervals, in each sample respectively; Adult Sample (SDB, OSA, and Arousal), and Pediatric Sample (SDB, HYP, Arousal, RERA). None of the 12 events evaluated were observed with PA, NA, or OA point-estimates vs 2/3 Majority Scoring that were 10% or lower in any of the scoring event types evaluated.
- For physiologic analysis events Endpoint 4, for SW and RR events, all three EnsoSleep subject device PA, NA, OA, percent epochs ≤ 2 brpm, and/or MAE point-estimates vs 2/3 Majority Scoring were observed to be statistically similar to the predicate device PA, NA, and OA point-estimates vs 2/3 Majority Scoring in all SW and RR event types evaluated. None of the PPG-SW events evaluated were observed with PA, NA, OA point-estimates vs 2/3 Majority Scoring that were 10% or lower in any of the EEG-SW sleep staging event types evaluated in the adult, pediatric, or in the RR Samples respectively, and a global minima PPG-SW performance statistic of 89% PA in the RR Sample (4% abs diff vs 93% EEG-SW). No statistically significant differences were observed between PPG-RR and EB-RR respiratory rate events vs 2/3 Majority Scoring; by ≥90% percent epochs with RR-value within ≤ 2 brpm of 2/3 Majority Scoring RR-value, and by MAE of RR value within ≤ 2 brpm of 2/3 Majority Scoring RR-value, when both were evaluated and compared in the RR Sample respectively. For TST the Deming Regression coefficient parameters Slope $\beta 1$ was near unity with $0.90 \leq \beta 1 \leq 1.10$, Intercept $\beta 0$ was near zero with $\beta 0 \leq 15$ minutes, the Bland-Altman absolute mean difference was near zero with MD within ≤15 mins, and Bland-Altman 95% absolute upper and lower limits of agreement were within <90 mins. No clinically significant deviations observed in PPG-TST or EEG-TST index values vs 2/3 Majority Scoring based the Deming regression coefficients, the average differences, the Bland-Altman 95% limits of agreement, or the two-sided 95% bootstrap confidence intervals, when compared to 2/3 Majority Scoring TST in each of the adult, pediatric, and RR samples respectively when comparing TST index performance.
- In supplemental clinical data and analyses provided with Endpoint 2, both the pediatric and adult samples showed a strong sleep apnea diagnostic agreement. The results showed no statistically significant difference in performance between the pediatric sample and both the predicate device and the adult sample performance which further demonstrated substantial equivalence in performance for the pediatric subgroup. The additional pediatric subgroups analyzed showed consistent results with prior pediatric study results reported in endpoints 1-4. For supplemental clinical data and analyses provided with Endpoint 4 the RR, adult, and pediatric sample groups met all criteria specified for both the Deming regression analysis and Bland-Altman analysis, with evaluated results that demonstrated strong clinical performance based on a Deming regression coefficient slope

β1 that was near unity and intercept β0 near zero, and all Bland-Altman limits of agreement were within 90 minutes and a mean difference within 15 minutes.

STUDY RESULTS

Sleep Staging Event Detection

The subject device EnsoSleep and predicate device EnsoSleep (K162627) clinical performance results compared for Endpoint 1, sleep staging. For all sleep staging event types evaluated in Endpoint 1, the point-estimates of the subject device PA, NA and OA event detection performance exceeded, were equivalent to, or were within 5% of the predicate device PA, NA and OA performance. The subject device PA, NA, and OA performance was observed to be statistically significantly greater in nearly all comparisons relative to the predicate device, showing a significant increase in Total Staging PA by 9% and resulting Total PA of 87% in Adult and 89% In Pediatric samples. The results confirm EnsoSleep achieves clinical performance for sleep staging positive, negative, and overall agreement that is substantially equivalent to the predicate device positive, negative, and overall agreement across all sleep stages.

		Adult Sample Pooled-Epochs EnsoSleep vs 2/3 Majority Sleep Staging Performance (K210034)				**Adult Sample Pooled-Epochs Predicate vs 2/3 Majority Sleep Staging Performance (K162627)**			
Overall-Epochs assigned by 2/3 Majority Scoring		**(N=100, 84,408 PSG epochs)**	**Percent Agreement (%) with two-sided 95% bootstrap median percentile method confidence intervals (R=2000)**			**(N=72, 59,719 PSG epochs)**	**Percent Agreement (%) with two-sided 95% bootstrap median percentile method confidence intervals (R=1000)**		
	Overall	Total	Positive	Negative	Overall	Total	Positive	Negative	Overall
	Wake	23,596	93.5% (93.1%, 93.8%)	97.2% (97.1%, 97.4%)	96.1% (96.0%, 96.3%)	17,459	86% (82%, 88%)	97% (95%, 98%)	94% (92%, 95%)
	N1	4,406	37.0% (35.6%, 38.5%)	98.3% (98.2%, 98.4%)	95.0% (94.8%, 95.1%)	3,293	41% (33%, 48%)	94% (93%, 96%)	91% (90%, 93%)
	N2	37,890	88.3% (87.9%, 88.6%)	89.3% (89.0%, 89.6%)	88.8% (88.6%, 89.0%)	26,839	77% (73%, 81%)	87% (85%, 90%)	83% (80%, 85%)
	N3	6,513	80.0% (79.0%, 81.0%)	96.3% (96.2%, 96.5%)	95.0% (94.9%, 95.2%)	5,587	81% (74%, 88%)	93% (91%, 95%)	92% (90%, 94%)
	REM	9,400	90.9% (90.4%, 91.5%)	99.3% (99.2%, 99.3%)	98.3% (98.2%, 98.4%)	6,541	79% (72%, 84%)	99% (98%, 99%)	96% (96%, 97%)
	Total	81,805	86.6% (86.4%, 86.9%)			59,719	78% (77%, 80%)		
	None	2,603	-			1,432	-		

		Pediatric Sample Pooled-Epochs EnsoSleep vs 2/3 Majority Sleep Staging Performance (K210034)				Adult Sample Pooled-Epochs Predicate vs 2/3 Majority Sleep Staging Performance (K162627)			
		(N=47, 38,568 PSG epochs)	Percent Agreement (%) with two-sided 95% bootstrap median percentile method confidence intervals (R=2000)			(N=72, 59,719 PSG epochs)	Percent Agreement (%) with two-sided 95% bootstrap median percentile method confidence intervals (R=1000)		
Overall-Epochs assigned by 2/3 Majority Scoring	Overall	Total	Positive	Negative	Overall	Total	Positive	Negative	Overall
	Wake	7,867	93.1% (92.5%, 93.6%)	99.2% (99.1%, 99.3%)	97.9% (97.8%, 98.1%)	17,459	86% (82%, 88%)	97% (95%, 98%)	94% (92%, 95%)
	N1	1,263	43.2% (40.4%, 45.9%)	98.8% (98.7%, 99.0%)	97.0% (96.8%, 97.1%)	3,293	41% (33%, 48%)	94% (93%, 96%)	91% (90%, 93%)
	N2	17,542	92.6% (92.3%, 93.0%)	89.4% (89.0%, 89.8%)	90.9% (90.6%, 91.2%)	26,839	77% (73%, 81%)	87% (85%, 90%)	83% (80%, 85%)
	N3	6,852	92.3% (91.6%, 92.9%)	97.5% (97.3%, 97.7%)	96.6% (96.4%, 96.7%)	5,587	81% (74%, 88%)	93% (91%, 95%)	92% (90%, 94%)
	REM	4,278	80.9% (79.6%, 82.0%)	99.1% (99.0%, 99.2%)	97.0% (96.8%, 97.2%)	6,541	79% (72%, 84%)	99% (98%, 99%)	96% (96%, 97%)
	Total	37,802	89.7% (89.4%, 90.0%)			59,719	78% (77%, 80%)		
	None	766	-			1,432	-		

Adult OSA Severity Subgroup Index

The subject device EnsoSleep and predicate device EnsoSleep (K162627) clinical performance results compared for Endpoint 2, sleep apnea diagnostic agreement. For all diagnostic agreement experiments evaluated in Endpoint 2, mild-AHI and moderate-AHI subject device PA, NA, and OA performance exceeded, were equivalent to, or were within 10% of the predicate device PA, NA, and OA performance, with statistically significant differences (greater performance) observed for NA and OA in mild-AHI. On the basis that the subject device met or exceeded objective PA, NA, and OA performance goals for sleep apnea diagnostic in all comparisons, EnsoSleep is considered substantially equivalent to the predicate device agreement for the analyzed OSA diagnostic severity groups.

Adult Sample Per-Patient EnsoSleep and Predicate Sleep Apnea Diagnostic Agreement								
	EnsoSleep vs 2/3 Majority Scoring Adult Sample (K210034)				**Predicate vs 2/3 Majority Scoring Adult Sample (K162627)**			
	EnsoSleep		**EnsoSleep REM**		**Predicate**		**Predicate REM**	
	AHI ≥ 5	**AHI ≥ 15**	**AHI ≥ 5**	**AHI ≥ 15**	**AHI ≥ 5**	**AHI ≥ 15**	**AHI ≥ 5**	**AHI ≥ 15**
Sample size (n)	100	100	100	100	72	72	72	72
Positive Percent Agreement (%) with two-sided 95% bootstrap median percentile CI's (R=2000)	94.4% (89.0%, 98.7%)	94.0% (85.7%, 100.0%)	86.7% (77.6%, 95.0%)	81.5% (65.0%, 95.5.%)	91% (82%, 98%)	95% (83%, 100%)	83% (72%, 94%)	79% (56%, 94%)
Negative Percent Agreement (%) with two-sided 95% bootstrap median percentile CI's (R=2000)	89.7% (75.8%, 100.0%)	96.3% (90.9%, 100.0%)	83.0% (71.1%, 93.6%)	93.3% (86.8%, 98.6%)	76% (61%, 90%)	98% (94%, 100%)	89% (75%, 97%)	96% (87%, 100%)
Overall Percent Agreement (%) with two-sided 95% bootstrap median percentile CI's (R=2000)	93.0% (88.0%, 97.0%)	95.0% (90.0%, 100.0%)	85.0% (78.0%, 92.0%)	90.0% (84.0%, 95.0%)	85% (77%, 92%)	97% (93%, 100%)	86% (76%, 93%)	92% (85%, 97%)
Likelihood ratio (+)	9.146 (3.879, ∞)	25.458 (10.154, ∞)	5.069 (2.962, 13.597)	12.052 (5.977, 55.250)	3.76	52.25	7.71	22.00
Liklihood ratio (-)	0.062 (0.014, 0.127)	0.062 (0.000, 0.151)	0.162 (0.060, 0.278)	0.198 (0.049, 0.384)	0.12	0.05	0.19	0.22

Pediatric OSA Severity Subgroup

The subject device EnsoSleep and predicate device EnsoSleep (K162627) clinical performance results compared for supplemental study results of Endpoint 2, pediatric and predicate adult sleep apnea diagnostic agreement. The supplemental pediatric subgroup statistical analysis results showed strong sleep apnea diagnostic agreement performance across a range of clinically relevant subgroup thresholds appropriate for pediatric patients. Based on review of each of the agreement performance measures and the two-sided 95% bootstrap CIs, observations confirmed no statistically significant differences in pediatric patient PA, NA, or OA performance, neither by relative nor absolute comparisons, to the predicate device adult patient PA, NA, or OA performance observed. On the basis that EnsoSleep met or exceeded objective performance goals for the additional pediatric validation data provides further support that the device is substantially equivalent in pediatric subjects when compared to the performance of adult subjects in the predicate device.

	EnsoSleep vs 2/3 Majority Scoring Pediatric Sample				**Predicate vs 2/3 Majority Scoring Adult Sample**	
	EnsoSleep (K210034)				**Predicate (K162627)**	
	AHI ≥ 1	**AHI ≥ 5**	**AHI ≥ 10**	**AHI ≥ 15**	**AHI ≥ 5**	**AHI ≥ 15**
Sample size (n)	47	47	47	47	72	72
Positive Percent Agreement (%) with two-sided 95% bootstrap median percentile CI's (R=2000)	94.4% (85.3%, 100.0%)	90.5% (75.0%, 100.0%)	78.6% (45.5%, 100.0%)	85.7% (44.4%, 100.0%)	91% (82%, 98%)	95% (83%, 100%)
Negative Percent Agreement (%) with two-sided 95% bootstrap median percentile CI's (R=2000)	77.8% (50.0%, 100.0%)	100.0% (100.0%, 100.0%)	94.9% (86.5%, 100.0%)	100.0% (100.0%, 100.0%)	76% (61%, 90%)	98% (94%, 100%)
Overall Percent Agreement (%) with two-sided 95% bootstrap median percentile CI's (R=2000)	89.4% (80.9%, 97.9%)	95.7% (89.4%, 100.0%)	91.5% (83.0%, 97.9%)	97.9% (93.6%, 100.0%)	85% (77%, 92%)	97% (93%, 100%)
Likelihood ratio (+)	4.190 (1.892, ∞)	∞ (∞, ∞)	15.692 (5.067, ∞)	∞ (∞,∞)	3.76	52.25
Liklihood ratio (-)	0.070 (0.000, 0.205)	0.095 (0.000, 0.250)	0.222 (0.000, 0.578)	0.143 (0.000, 0.556)	0.12	0.05

Sleep Scoring Event Detection

The subject device EnsoSleep, predicate device EnsoSleep (K162627), and reference device MICHELE Sleep Scoring (K112102) clinical performance results compared for Endpoint 3, event detection agreement. For hypopneas and central apneas, the MICHELE Sleep Scoring performance testing did not calculate OA for individual event types and as such only PA and NA comparisons were established. For all event detection experiments including SDB, OSA, HYP, CSA, Arousal, and Leg Movement event types, the point-estimates of the subject device PA, NA and OA event detection performance exceeded, were equivalent to, or were within 5% of the reference device PA, NA and OA performance, with statistically significant differences (greater performance) observed in a majority of cases. On the basis that EnsoSleep met or exceeded objective PA, NA, and OA performance goals for these event types in all comparisons the device is considered substantially equivalent to the predicate device SDB, OSA, HYP, CSA, Arousal, and Leg Movement event detection performance.

Event Detection Clinical Performance Comparisons		**Adult Sample Pooled-Epochs EnsoSleep (K210034) vs 2/3 Majority Event Detection Performance**				**Adult Sample Overall-Pooled Predicate (K162627) and Reference Predicate (K112102) vs 2/3 Majority Event Detection Performance**			
		(N=100, 84,408 PSG epochs)	**Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=2000 resamples)**			**(N=72 subjects, 59719 epochs)**	**Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=1000 resamples)**		
		Total Epochs	**Positive Agree-ment (PA)**	**Negative Agree-ment (NA)**	**Overall Agree-ment (OA)**	**Total Epochs**	**Positive Agree-ment (PA)**	**Negative Agree-ment (NA)**	**Overall Agree-ment (OA)**
Overall-Epochs assigned by 2/3 Majority Scoring	**Sleep Disordered Breathing Events**	8108	75.4% (74.5%, 76.3%)	97.0% (96.9%, 97.2%)	94.9% (94.8%, 95.1%)	4705	67% (58%, 75%)	93% (92%, 94%)	91% (90%, 92%)
	Hypopnea Events	4420	66.3% (64.9%, 67.6%)	97.1% (97.0%, 97.2%)	95.5% (95.4%, 95.6%)	1822	60.3%	97.6%	n/r
	Obstructive Apnea Events	1659	74.1% (72.1%, 76.1%)	99.3% (99.2%, 99.3%)	98.8% (98.7%, 98.8%)	1066	53% (35%, 71%)	97% (96%, 97%)	96% (95%, 97%)
	Central Apnea Events	1505	65.3% (63.1%, 67.6%)	99.5% (99.5%, 99.6%)	98.9% (98.8%, 99.0%)	177	63.8%	99.6%	n/r
	Arousal Events	9047	73.6% (72.7%, 74.5%)	95.6% (95.5%, 95.7%)	93.2% (93.1%, 93.4%)	7686	66% (61%, 71%)	90% (88%, 91%)	87% (85%, 88%)
	Leg Movement Events	6018	82.0% (81.0%, 83.0%)	92.4% (92.2%, 92.6%)	91.7% (91.5%, 91.8%)	5796	71% (60%, 80%)	90% (89%, 92%)	89% (87%, 90%)

Event Detection Clinical Performance Comparisons		Pediatric Sample Pooled-Epochs EnsoSleep (K210034) vs 2/3 Majority Event Detection Performance				Adult Sample Overall-Pooled Predicate (K162627) and Reference Predicate (K112102) vs 2/3 Majority Event Detection Performance			
		(N=47, 38,568 PSG epochs)	Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=2000 resamples)			(N=72 subjects, 59719 epochs)	Bootstrapped point-estimate of median Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=1000 resamples)		
		Total Epochs	Positive Agree-ment (PA)	Negative Agree-ment (NA)	Overall Agree-ment (OA)	Total Epochs	Positive Agree-ment (PA)	Negative Agree-ment (NA)	Overall Agree-ment (OA)
Overall-Epochs assigned by 2/3 Majority Scoring	Sleep Disordered Breathing Events	1480	72.7% (70.4%, 74.9%)	98.6% (98.4%, 98.7%)	97.6% (97.4%, 97.7%)	4705	67% (58%, 75%)	93% (92%, 94%)	91% (90%, 92%)
	Hypopnea Events	1046	68.8% (66.0%, 71.6%)	98.9% (98.8%, 99.0%)	98.0% (97.9%, 98.2%)	1822	60.3%	97.6%	n/r
	Obstructive Apnea Events	105	45.5% (36.0%, 54.8%)	99.7% (99.6%, 99.7%)	99.5% (99.5%, 99.6%)	1066	53% (35%, 71%)	97% (96%, 97%)	96% (95%, 97%)
	Central Apnea Events	277	68.9% (63.5%, 74.1%)	99.7% (99.7%, 99.8%)	99.5% (99.4%, 99.6%)	177	63.8%	99.6%	n/r
	Arousal Events	3018	78.6% (77.1%, 80.0%)	97.0% (96.8%, 97.2%)	95.5% (95.3%, 95.7%)	7686	66% (61%, 71%)	90% (88%, 91%)	87% (85%, 88%)
	Leg Movement Events	1247	66.0% (63.4%, 68.6%)	95.5% (95.3%, 95.7%)	94.5% (94.3%, 94.8%)	5796	71% (60%, 80%)	90% (89%, 92%)	89% (87%, 90%)

Total Sleep Time

The subject device EnsoSleep clinical performance results compared for supplemental study results of Endpoint 4, Total Sleep Time (TST) comparison. The reported results and observations showed that the Deming regression analysis and Bland-Altman mean difference analysis met or exceeded all acceptance criteria for each experiment type relative to the predicate device TST index agreement performance. The subject device PPG-TST and EEG-TST demonstrated statistically similar performance in all of the RR, adult, and pediatric samples respectively, demonstrated no clinically significant deviations in performance based on the Bootstrap two-sided 95% confidence intervals for the observed mean differences, upper and lower limits of agreement, or regression coefficient parameters, and met or exceeded all objective performance evaluation criteria specified by the clinical study protocol and the supplemental clinical study analyses. Thus, EnsoSleep TST index agreement performance is determined to be substantially equivalent to the predicate based on acceptance criteria, and safe and effective for use.

Per-Patient EnsoSleep Adult, Pediatric, and RR Sample Total Sleep Time Index Performance (K210034)	**EnsoSleep PPG-TST vs 2/3 Majority Scoring TST Respiratory Rate Sample**	**EnsoSleep EEG-TST vs 2/3 Majority Scoring TST Respiratory Rate Sample**	**EnsoSleep EEG-TST vs 2/3 Majority Scoring TST Adult Sample**	**EnsoSleep EEG-TST vs 2/3 Majority Scoring TST Pediatric Sample**
Deming Regression plot Slope β1 (DRpS-β1) with two-sided 95% bootstrap median percentile CI's (R=2000)	0.964 (0.860, 1.067)	0.984 (0.925, 1.023)	1.037 (0.974, 1.201)	1.006 (0.988, 1.018)
Deming Regression plot Intercept β0 (DRpI-β0) [hours] with two-sided 95% bootstrap median percentile CI's (R=2000)	0.089 (-0.484, 0.663)	0.156 (-0.071, 0.504)	-0.181 (-1.101, 0.182)	0.021 (-0.034, 0.134)
Bland-Altman difference plot mean difference (BADp-MD) [minutes] with 95% Limits of Agreement (LOAs) for 1.96 standard deviations (1.96SD) of the average difference including two-sided 95% bootstrap-t CI's (R=2000) with the MD, upper (BADp-ULOA) [minutes], and lower (BADp-LLOA) [minutes] limits of agreement	MD: 5.380 (2.372, 8.475)	MD: -4.785 (-6.131, -2.237)	MD: 0.515 (-4.173, 2.331)	MD: -3.255 (-4.411, -1.472)
	ULOA: 73.463 (68.332, 78.743)	ULOA: 32.922 (30.625, 37.269)	ULOA: 57.750 (49.751, 60.849)	ULOA: 10.654 (9.310, 12.728)
	LLOA: -62.703 (-67.835, -57.423)	LLOA: -42.492 (-44.789, -38.145)	LLOA: -56.720 (-64.718, -53.621)	LLOA: -17.164 (-18.508, -15.091)

Clinical Performance Conclusion

Non-clinical and clinical verification, validation, and performance testing were conducted in accordance with FDA's relevant recommendations to confirm the device design met all specifications, user needs for qualified clinical and non-clinical users.

EnsoSleep has passed all of the verification and validation tests and provided clinical performance testing results that demonstrate safety, effectiveness for the intended use of the device and that the performance data demonstrate that the new technological characteristics proposed in this 510(k) submission are substantially equivalent to the predicate device.

Newly introduced sleep staging, scoring, and physiological signal-based analysis to provide event detection and sleep apnea diagnostic severity agreement performance were tested with

acceptable methods and provided data to support a determination of substantially equivalent as compared to the predicate device based on the indications for use and pre-specified acceptance criteria.

The EnsoSleep subject device performance is statistically similar to the predicate device performance, by comparison to a double-blind, prospective 2/3 Majority Scoring panel consensus reference of independent, qualified sleep technologist scorers, providing additional objective evidence that EnsoSleep is safe and effective within the indications for use. Based on the submitted clinical performance validation testing protocols, controls, methodology, evidence, and results, EnsoSleep and its sleep staging event, scoring event, physiological analysis for event detection and sleep apnea severity diagnostic agreement demonstrate substantial equivalence to the predicate device.

CONCLUSIONS
The subject device EnsoSleep and the predicate have the same intended use and are similar in basic technological characteristics to the predicate device EnsoSleep K162627. The new device characteristics do not raise different questions of safety and effectiveness. The subject device EnsoSleep includes a new target patient population (pediatrics ages 13 and up for in-clinic and hospital PSG) and use of home sleep testing with adult patients to produce automated event detection of previously recorded PSGs.

A clinical study was performed on retrospective data of adults (18 years and older) and pediatrics (13-17 years old) and submitted in support of the new claims for the subject device. The study examined sleep scoring accuracy including hypopnea, apnea, arousal, respiratory, and movement events. One hundred adult and 47 pediatric retrospective sleep studies were scored by three clinicians and compared to the subject device automated scoring and compared to predicate and reference predicate devices. The results of the study show that the subject device automated scoring performs equal to or better than the predicate and reference devices. The clinical study confirmed the safety and effectiveness of the subject device and there were no complications or contraindications found during the study.

EnsoSleep has passed the aforementioned verification and validation tests and provided clinical performance testing results with a clinical dataset in order to demonstrate safety and effectiveness as compared to the predicate device. It is therefore concluded that the subject EnsoSleep device is substantially equivalent to the predicate EnsoSleep device.