October 9, 2026

Neurotronics, LLC
James Smith
Director of Quality and Regulatory
13800 Tech City Cir., Suite 400
Alachua, Florida 32615

Re: K261521
Trade/Device Name: Sleep Analysis Module
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: September 11, 2026
Received: September 11, 2026

Dear James Smith:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Patrick Antkowiak -S

Patrick Antkowiak, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261521

Device Name
Sleep Analysis Module

Indications for Use *(Describe)*
The Sleep Analysis Module is a software-only medical device provided as a software library intended to be integrated into a host application that analyzes physiological data. The device is intended for use by, or under the supervision of, a clinician to aid in the diagnosis of sleep disorders in patients 18 years of age and older.

The Sleep Analysis Module is intended to analyze a photoplethysmography (PPG) signal and calculate Total Sleep Time (TST).

TST derived from a PPG signal is an estimate of sleep duration and is not intended for use when electroencephalogram (EEG), electrooculogram (EOG), and electromyogram (EMG) signals are available and full sleep staging is possible. PPG-derived TST is not intended to serve as the sole or primary basis for the diagnosis of any sleep disorder.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Traditional 510(k) Summary K261521

Submitter Information

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Primary Contact: James “Cody” Smith
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Email: quality@neurotronics.com

Date Prepared: October 8, 2026

Regulatory Information

Submission Number: K261521
Trade Name: Sleep Analysis Module
Common Name: Automatic Event Detection Software for Polysomnograph with Electroencephalograph
Classification Name: Electroencephalograph
FDA Product Code: OLZ
CFR References: 21 CFR 882.1400
Device Classification: II
Review Panel: Neurology

Predicate Device

Submission Number: K210034
Device Name: EnsoSleep

Subject Device Description

The Sleep Analysis Module (SAM) is a software-only medical device provided as a software library for integration into host applications that analyze physiological data. SAM includes a Total Sleep Time (TST) algorithm that analyzes a photoplethysmography (PPG) signal to estimate TST and aid healthcare professionals in the evaluation of sleep disorders.

SAM does not include a graphical user interface and does not operate independently as a standalone user-facing application. The host application communicates with SAM through a defined application programming interface (API) and is responsible for supplying input data, receiving outputs, displaying results, and managing the associated workflow. SAM does not store or display data.

The TST algorithm processes PPG input data and generates an estimated TST value. SAM may also provide epoch-level sleep/wake classifications for 30-second epochs as part of the algorithm output. These classifications support the derivation of TST and are provided to the host application through the API.

The TST algorithm incorporates a locked machine learning model as one component of its processing. The model is fixed at the time of release and does not adapt, retrain, or self-modify after deployment.

Indications for Use

The Sleep Analysis Module is a software-only medical device provided as a software library intended to be integrated into a host application that analyzes physiological data. The device is intended for use by, or under the supervision of, a clinician to aid in the diagnosis of sleep disorders in patients 18 years of age and older.

The Sleep Analysis Module is intended to analyze a photoplethysmography (PPG) signal and calculate Total Sleep Time (TST).

TST derived from a PPG signal is an estimate of sleep duration and is not intended for use when electroencephalogram (EEG), electrooculogram (EOG), and electromyogram (EMG) signals are available and full sleep staging is possible. PPG-derived TST is not intended to serve as the sole or primary basis for the diagnosis of any sleep disorder.

Substantial Equivalence Table of Comparison

The table below compares the indications for use and technological characteristics of the subject and predicate devices. Any differences are discussed, and this summary table demonstrates that the Sleep Analysis Module is substantially equivalent to the predicate device, EnsoSleep.

Device Characteristic	**Subject Device Sleep Analysis Module (K261521)**	**Predicate Device EnsoSleep (K210034)**	**Comment**
510(k) reference	K261521	K210034	
Product Name	Sleep Analysis Module	EnsoSleep	
Manufacturer	Neurotronics, LLC	EnsoData, Inc.	
FDA Product Code	OLZ	OLZ	Same
CFR Reference	21 CFR 882.1400 - Electroencephalograph	21 CFR 882.1400 - Electroencephalograph	Same
Device Class	II	II	Same
Prescription or OTC	Prescription Only	Prescription Only	Same

Device Characteristic	**Subject Device Sleep Analysis Module (K261521)**	**Predicate Device EnsoSleep (K210034)**	**Comment**
Indications for use statement	The Sleep Analysis Module is a software-only medical device provided as a software library intended to be integrated into a host application that analyzes physiological data. The device is intended for use by, or under the supervision of, a clinician to aid in the diagnosis of sleep disorders in patients 18 years of age and older. The Sleep Analysis Module is intended to analyze a photoplethysmography (PPG) signal and calculate Total Sleep Time (TST). TST derived from a PPG signal is an estimate of sleep duration and is not intended for use when electroencephalogram (EEG), electrooculogram (EOG), and electromyogram (EMG) signals are available and full sleep staging is possible. PPG-derived TST is not intended to serve as the sole or primary basis for the diagnosis of any sleep disorder.	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. 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.	Similar; Predicate device can score more events than the subject device. These additional events are listed by the predicate device.

Device Characteristic	**Subject Device Sleep Analysis Module (K261521)**	**Predicate Device EnsoSleep (K210034)**	**Comment**
Intended Use	Analyze a photoplethysmography (PPG) signal and calculate Total Sleep Time (TST) to aid physicians in the diagnosis of sleep disorders.	Analyze physiological data and score sleep study results to assess sleep quality and as an aid for physicians in the diagnosis of sleep disorders and respiratory related sleep disorders.	Subject device cannot assess sleep quality. Reduction in scope does not affect safety or effectiveness as the device is intended to be used to score TST only. Predicate device specifically lists "respiratory related sleep disorders", but that would be fall under the broad umbrella of "sleep disorders."
Target Population	Patients 18 years and older	Adults and Children 13 years and older	Subject device is intended for a narrower population (18 years and older). Reduction in scope does not affect safety or effectiveness.
Environment for Use	Data analysis performed by, or under the supervision of, a clinician. No limitation on where data is acquired.	Data analysis performed under the supervision of a clinician. No limitation on where data is acquired.	Same
Principle of Operation	Software as a Medical Device (SaMD) library accessed through an Application Programming Interface (API) by a host device that has a User Interface (UI).	Software as a Medical Device (SaMD) that has a Graphical User Interface (GUI)	Both devices are SaMD and only differ in the way they interface.
Interface	Application Programming Interface (API)	Graphical User Interface (GUI)	Modified; Subject device communicates with its host application through an API. The parent device would have an interface that presents the calculated values to the user. Predicate device directly presents the calculated values to the user through a GUI. Differences do not affect safety or effectiveness.
Compatibility	Library can be used by software running on a supported Operating System: • Windows 10 or later • Linux	Software runs on a PC with a supported Operating System: • Windows 7 or later • Windows Server 2012 or later	Subject device can be used with a Linux operating system and the Predicate device cannot.
Algorithms	Machine learning based algorithm	AI-driven algorithms	Both devices use Artificial Intelligence (AI) in their algorithms. Subject device just specifies a branch of AI.
Model Behavior	Locked (no post-deployment learning)	Locked (no post-deployment learning)	Same

Device Characteristic	Subject Device Sleep Analysis Module (K261521)	Predicate Device EnsoSleep (K210034)	Comment
Total Sleep Time (TST) - Outputs Parameters	Total Sleep Time (TST) and Sleep-Wake epochs	Total Sleep Time (TST) and Sleep-Wake epochs	Same
Total Sleep Time (TST) - Input Signals	Photoplethysmogram (PPG)	Photoplethysmogram (PPG)	Same
Data Format	Signal is passed to library as an array of double-precision floating point samples. Signal source can be from any file type.	Software analyzes EDF files	Modified; Subject device is intended to be integrated into a host application, so the signal is input as an array. The Predicate device only analyzes EDF files. Differences do not affect safety or effectiveness.

Performance Testing

Performance testing was conducted to support a determination of substantial equivalence for the Sleep Analysis Module. Testing included software verification, representative host integration validation, design validation, and clinical performance validation.

Nonclinical testing was performed on the Sleep Analysis Module and confirmed that the software met its requirements, including algorithm accuracy, input validation, error handling, UDI and version information, static code analysis, labeling/documentation review, and representative host integration. Host integration validation confirmed that a host can provide the required PPG input data, receive and report Total Sleep Time (TST), apply monitoring time behavior, handle insufficient valid signal duration, and address intended-use limitations. All non-clinical and integration validation tests were completed and found acceptable, with no unacceptable tests, open tests, or unresolved known issues.

Clinical performance validation was conducted using a retrospective, blinded, paired method-comparison study with previously recorded polysomnography (PSG) data. The final analysis population included 146 studies from individuals 18 years of age and older, with the distribution of subjects by age range shown in the table below. Reference TST was derived from independent manual PSG scoring by three qualified, blinded scorers using a two-out-of-three consensus method.

Age	Number	Percentage
18-39	25	17.1%
40-49	30	20.5%
50-59	34	23.3%
60-69	35	24.0%
70+	22	15.1%

The primary clinical performance analysis compared algorithm-derived TST to reference PSG-derived TST using Bland-Altman analysis and Deming regression. All pre-specified primary performance endpoints met acceptance criteria (which were based on point estimates, and not confidence intervals) as shown below. Additionally, subgroup analyses did not identify statistically significant differences in TST prediction error across evaluated sex, race/ethnicity, or geographic region subgroups. However, subgroup sample sizes were limited for some groups, and these analyses should be interpreted accordingly. The observed subgroup mean errors were descriptively evaluated and all fell within the ±15-minute criterion established for pooled systematic mean bias.

Endpoint	Acceptance Criterion	Result	Pass/Fail
Bland-Altman mean difference	$\|MD\| \leq 15$ minutes	+3.02 minutes	Pass
Lower limit of agreement	≥ -90 minutes	−77.63 minutes	Pass
Upper limit of agreement	$\leq +90$ minutes	+83.66 minutes	Pass
Deming regression slope	0.90–1.10	0.939	Pass
Deming regression intercept	$\|Intercept\| \leq 30$ minutes	24.35 minutes	Pass

Metric	SAM (N = 146)	EnsoSleep PPG-TST (N = 100)	Acceptance Criterion
Bland-Altman MD	+3.02 min	+5.38 min	$\|MD\| \leq 15$ min
Lower LOA	−77.63 min	−62.70 min	≥ -90 min
Upper LOA	+83.66 min	+73.46 min	$\leq +90$ min
Deming Slope (β_1)	0.939	0.964	0.90–1.10
Deming Intercept (β_0)	24.35 min	5.3 min	$\|\beta_0\| \leq 30$ min
Pearson r	0.844	—	—

It should be noted by users that this testing shows that the Lower limit of the of TST -77.63 minutes and Upper limit of +83.66 minutes is large respective of a sleep test in the target patient population. This information should simply be noted because in individual patients, this difference may be significant. The TST output alone is not a sole determinant but instead is used in the context of other information about the patient while applying clinical judgment.

Based on the results of nonclinical testing, representative host integration validation, design validation, and clinical performance validation, the Sleep Analysis Module performs as intended and supports a determination that the device is as safe and effective as the predicate device and does not raise different questions of safety or effectiveness.

Conclusion

The Sleep Analysis Module has the same intended use and similar technological characteristics as the predicate device, EnsoSleep (K210034). Differences between the subject device and predicate device, including the subject device's narrower output scope, software library architecture, API-based interface, supported operating systems, and input data format, do not raise different questions of safety or effectiveness.

Nonclinical verification and validation testing demonstrated that the Sleep Analysis Module performs as intended and meets its software requirements. Clinical performance validation demonstrated acceptable agreement between algorithm-derived Total Sleep Time (TST) and reference PSG-derived TST, with all pre-specified primary performance endpoints met.

Based on the comparison of intended use, technological characteristics, and performance testing, Neurotronics, LLC concludes that the Sleep Analysis Module is as safe and effective as the predicate device and is substantially equivalent to EnsoSleep (K210034).