December 14, 2025

Cadwell Industries, Inc
James Blevins
Product Manager, Sleep Diagnostics
909 N Kellogg St
Kennewick, Washington 99336

Re: K250851
Trade/Device Name: Hypnos (369054-200)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ, OLV
Dated: November 14, 2025
Received: November 14, 2025

Dear James Blevins:

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,

Patrick Antkowiak -S

for
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250851

Device Name

Hypnos (369054-200)

Indications for Use *(Describe)*

Cadwell Hypnos is a software application used for Polysomnography (PSG) and other clinical sleep studies. It is intended for use by research and clinical sleep professionals. It measures, records, displays, organizes, analyzes, summarizes, and retrieves physiological signals during sleep and wake used to assist in the assessment of sleep and the diagnosis of various sleep disorders including sleep related breathing disorders. The software can be used for analysis (computer-assisted as well as manual scoring of events), display, retrieval, summarization, reporting and networking of data received from devices used to monitor sleep related parameters.

Hypnos is indicated for use in all sleep disorders patient populations from neonate to adult, including infants, pediatrics and geriatric populations. Computer-assisted analysis features of the application are only intended for use on adults.

Hypnos is only indicated for use by trained medical professionals for the purpose of assessing sleep disorders.
Intended environments include hospitals, institutions, sleep centers, sleep clinics, and other sleep disorders testing environments.

Hypnos is NOT intended to be used to perform automatic diagnosis.

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.

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Hypnos 510(k) Summary

Submitter Information

Submitter Name:	Cadwell Industries, Inc. 909 N. Kellogg Street Kennewick, Washington 99336
Submitter Phone:	509-735-6481
Contact Person:	James Blevins Product Manager, Sleep Diagnostics
Date Summary Prepared:	February 28, 2025

Subject Device

Trade Name:	Hypnos
Common Name:	Standard Polysomnograph with Electroencephalograph
Classification Name:	21 CFR 882.1400, Electroencephalograph Class II
Product Code:	OLZ, OLV

Predicate Device

510(k) Number:	K142988
Trade Name:	Sleepware G3
Submitter Name:	Respironics
Classification Name:	21 CFR 882.1400, Electroencephalograph
Product Code:	OLZ, MNR, OLV

Reference Predicate Device

510(k) Number:	K210034
Trade Name:	EnsoSleep
Submitter Name:	EnsoData, Inc.
Classification Name:	21 CFR 882.1400, Electroencephalograph
Product Code:	OLZ

Device Description

Hypnos software is used to acquire, record, transmit, analyze, store, manage, report, and display physiological and environmental data collected by PSG and/or HSAT hardware. Hypnos software allows users to analyze signals both manually and using detectors to facilitate interpretation of a sleep study by a qualified user.

CADWELL® Hypnos 510(k) Summary

Indications for Use

Cadwell Hypnos is a software application used for Polysomnography (PSG) and other clinical sleep studies. It is intended for use by research and clinical sleep professionals. It measures, records, displays, organizes, analyzes, summarizes, and retrieves physiological signals during sleep and wake used to assist in the assessment of sleep and the diagnosis of various sleep disorders including sleep related breathing disorders. The software can be used for analysis (computer-assisted as well as manual scoring of events), display, retrieval, summarization, reporting and networking of data received from devices used to monitor sleep related parameters.

Hypnos is indicated for use in all sleep disorders patient populations from neonate to adult, including infants, pediatrics and geriatric populations. Computer-assisted analysis features of the application are only intended for use on adults.

Hypnos is only indicated for use by trained medical professionals for the purpose of assessing sleep disorders.

Intended environments include hospitals, institutions, sleep centers, sleep clinics, and other sleep disorders testing environments.

Hypnos is NOT intended to be used to perform automatic diagnosis.

CADWELL® Hypnos 510(k) Summary

Summary of Technological Characteristics and Comparison to the predicate device

Hypnos has equivalent technological characteristics to the predicate device. The following table provides a side-by-side comparison of the Indications for Use and technological characteristics of the subject and predicate devices.

Characteristics	***Subject Device Hypnos***	***Primary Predicate Device Sleepware G3 (K142988)***	***Reference Predicate EnsoSleep (K210034)***	***Discussion of Major Differences***
Device Class	Class II	Class II	Class II	No differences
Class Name	Electroencephalograph	Electroencephalograph	Electroencephalograph	No differences
Product Code	OLZ (Primary) = Automatic Event Detection Software for Polysomnograph with Electroencephalograph OLV = Standard polysomnograph with electroencephalograph	OLZ (Primary) = Automatic Event Detection Software for Polysomnograph with Electroencephalograph MNR = Ventilatory Effort Recorder OLV = Standard polysomnograph with electroencephalograph	OLZ (Primary) = Automatic Event Detection Software for Polysomnograph with Electroencephalograph	No differences. MNR does not apply to the subject device since it is software only.
Environment of Use	Sleep center (independent or hospital)	Sleep center (independent or hospital)	Sleep center (independent or hospital)	No differences
Intended User	Medical Professional	Medical Professional	Medical Professional	No differences
Target Patient Population	Neonate to adult, including infants, pediatrics and geriatric populations for manual review functions. Adult only for automatic event detection.	Infant or adult patients.	Pediatric and adult patients	No differences
Type of Use	Prescription use only	Prescription use only	Prescription use only	No differences

CADWELL® Hypnos 510(k) Summary

Characteristics	*Subject Device Hypnos*	*Primary Predicate Device Sleepware G3 (K142988)*	*Reference Predicate EnsoSleep (K210034)*	*Discussion of Major Differences*
Indications for Use	Cadwell Hypnos is a software application used for Polysomnography (PSG) and other clinical sleep studies. It is intended for use by research and clinical sleep professionals. It measures, records, displays, organizes, analyzes, summarizes, and retrieves physiological signals during sleep and wake used to assist in the assessment of sleep and the diagnosis of various sleep disorders including sleep related breathing disorders. The software can be used for analysis (computer-assisted as well as manual scoring of events), display, retrieval, summarization, reporting and networking of data received from devices used to monitor sleep related parameters. Hypnos is indicated for use in all sleep disorders patient populations from neonate to adult, including infants, pediatrics and geriatric populations. Computer-assisted analysis features of the application are only intended for use	Sleepware G3 is a software application used for analysis (automatic and manual scoring), display, retrieval, summarization, report generation and networking of data received from monitoring devices used to categorize sleep related events that help aid in the diagnosis of sleep related disorders. It is indicated for use with infant or adult patients in a clinical environment by or on the order of a physician. The optional Somnolyzer Inside scoring package has the same intended use as Sleepware G3, but is indicated for use with adult patients only.	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.	No difference to the primary predicate. Hypnos was specifically designed to enable clinical users to record, review and manually annotate PSG studies on neonate, infant, pediatric and adult patient populations. The software includes controls that are defaulted to industry standards for all age populations and are adjustable based on the discretion of the clinician. The computer-assisted marking feature in Hypnos is only indicated for use in Adult patients.

Characteristics	*Subject Device Hypnos*	*Primary Predicate Device Sleepware G3 (K142988)*	*Reference Predicate EnsoSleep (K210034)*	*Discussion of Major Differences*
	on adults. Hypnos is only indicated for use by trained medical professionals for the purpose of assessing sleep disorders. Intended environments include hospitals, institutions, sleep centers, sleep clinics, and other sleep disorders testing environments. Hypnos is NOT intended to be used to perform automatic diagnosis.		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.	
User input	Mouse/keyboard	Mouse/keyboard	Mouse/keyboard	No differences
Acquire, display, store, and archive PSG data	Yes	Yes	Yes	No differences
Data Collection	By separate acquisition hardware	By separate acquisition hardware	By separate acquisition hardware	No differences
FFT Analysis	Yes	Yes	Yes	No differences

CADWELL® Hypnos 510(k) Summary

Characteristics	*Subject Device Hypnos*	*Primary Predicate Device Sleepware G3 (K142988)*	*Reference Predicate EnsoSleep (K210034)*	*Discussion of Major Differences*
Software Detectors				
Respiratory event marking	Yes	Yes	Yes	No differences
Sleep staging/ scoring	Yes	Yes	Yes	No differences
Arousal event marking	Yes	Yes	Yes	No differences
Limb Movements event marking	Yes	Yes	Yes	No differences
Snore event marking	Yes	Yes	Yes	No differences
Oxygen Desaturation event marking	Yes	Yes	Yes	No differences
Heart Rate data trend & summary (including Heart Rate Variability)	Yes	Yes	Yes	No differences
CO2 data trend & summary	Yes	Yes	Yes	No differences
Associate related events	Yes	Yes	Yes	No differences
Derived respiratory traces	Yes	Yes	Yes	No differences
Synchronized patient video	Yes	Yes	Yes	No differences
Oximetry data display and reporting	Yes	Yes	Yes	No differences
Audio/ Visual Alerts On Calibrated Channels	Yes	Yes	Yes	No differences
Signals recorded (output)	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC	Respiratory Effort (abdomen and chest) Airflow Pressure Snore Body Position Pulse Rate Oximeter ECG EEG EMG EOG DC	No differences

CADWELL® Hypnos 510(k) Summary

Characteristics	*Subject Device Hypnos*	*Primary Predicate Device Sleepware G3 (K142988)*	*Reference Predicate EnsoSleep (K210034)*	*Discussion of Major Differences*
	Leg Movement Other signals for sleep studies	Leg Movement Other signals for sleep studies	Leg Movement Other signals for sleep studies Actigraphy PPG Esophogeal Manometry	
Report generation including counts indexes, max/min/average/duration, range based data summaries. Numeric & graphical representations	Yes, customizable templates	Yes, customizable templates	Yes, customizable templates	No differences
Standard of Scoring	The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events	The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events	The American Academy of Sleep Medicine (AASM) Manual for the Scoring of Sleep and Associated Events	No differences

Hypnos 510(k) Summary

Summary of Non-clinical Testing

FDA-recognized standards were applied throughout the design process of Hypnos. All verification, validation, and usability testing has been performed per the design requirements. Passing results support the intended use of Hypnos and ensures adequate safety, effectiveness and reliability.

Software testing was conducted in accordance with IEC 62304:2015-06.

Risk Management activities were conducted per ISO 14971:2019.

Usability testing is in accordance with IEC 62366-1:2020-06

Information to be provided to the User is in accordance with ISO 20417:2021-04 Corrected version 2021-12

The features of Hypnos have been compared with the predicate in order to demonstrate substantial equivalence. Specifically, both software applications have equivalent primary functions, including the following: opening and selecting existing sleep studies; displaying and navigating sleep study data/signals; manually scoring/annotating sleep study data by adding events/markers; facilitating the use of AASM standards; creating trend/summary overviews and interpretation reports; interfacing to analysis tools, and saving/storing scored recordings. Both applications visualize signals and events in equivalent ways, allow equivalent edits of scored events, and provide equivalent basic scoring and physician information via overviews and indexes.

Summary of Clinical Testing

Methodology

Our data included analysis of 42,972 recorded epochs, of which 36,088 were scored. These studies were chosen at random from existing sleep studies of acceptable signal quality from accredited labs where analysis had been performed by EnsoSleep (K210034) and had not been edited by human scorers. Studies were chosen at random from sleep labs independent of Cadwell.

The studies were copied with annotations from the EnsoSleep analysis extracted. Annotations were then stripped from the studies and Hypnos analyzers were run using default settings based on recommendations from the AASM and then events were compared between the two analysis sets.

Results

The results of the performance testing indicate that the computer-assisted scoring in the Hypnos subject device performs equivalently to the reference predicate device, with general event annotation above 80% across all valid clinical event types. There were no complications or contraindications found during the study. Individual performance metrics for each detector can be found in the tables below along with the Confidence Interval at 95% (95% CI):

Respiratory Events	Median	Overall	Over Detection	95% CI
Apnea	98.1%	96.7%	3.0%	**±1.06 [95.64%, 97.76%]**
Obstructive Apnea	98.1%	96.0%	4.3%	**±1.52 [94.78%, 97.52%]**
Central Apnea	99.4%	98.1%	0.6%	**±1.16 [96.94%, 99.26%]**
Hypopnea	89.1%	89.3%	10.1%	**±1.82 [94.48%, 97.52%]**
Respiratory Events	**88.6%**	**88.6%**	**10.8%**	**±1.76 [86.84%, 90.36%]**

Desaturation	Median	Overall	Over Detection	95% CI
Desaturation	**97.9%**	**97.3%**	**2.7%**	**±0.61 [96.69%,97.91%]**

Heart Rate	Median	Overall	Over Detection	95% CI
Heart Rate	**100.0%**	**99.8%**	**0.1%**	**±0.15 [99.65%,99.95%]**

Limb Movements	Median	Overall	Over Detection	95% CI
LM	88.4%	87.4%	4.2%	**±2.83 [84.57%,90.23%]**
PLM	93.4%	91.3%	1.8%	**±2.61 [88.69%,93.91%]**
PLMS Series	**99.1%**	**98.9%**	**0.5%**	**±0.33 [98.57%,99.23%]**

Conclusion

The Intended Use Comparison, the Technical Comparison, and Performance Testing Data results indicate that Hypnos presents no new questions of safety and effectiveness and is substantially equivalent to the legally marketed predicate devices.