July 15, 2026

Huneo, LLC
Philip Ryder
CEO
35000 Chardon Rd.
Willoughby Hills, Ohio 44094

Re: K260050
Trade/Device Name: WRAP System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, OLV, OLZ
Dated: June 15, 2026
Received: January 8, 2026

Dear Philip Ryder:

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 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

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)*

K260050

Device Name

WRAP System

Indications for Use *(Describe)*

The Wireless Realtime Attended Polysomnogram (WRAP) System measures and records multiple physiological parameters from a patient during a sleep study and its autoscoring algorithm scores sleep stages automatically. These recorded physiological parameters are used by clinicians to assist in evaluating the diagnosis of sleep disorders. The WRAP System is intended to be used on a patient, who has been prescribed a sleep study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but may be applied by a layperson. The recorded data will be made available to a healthcare professional to assist in the diagnosis of sleep disorders. The device is intended to be used for adults.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) SUMMARY
(21 CFR 807.92(C))

Applicant Name/Address: Huneo, LLC
35000 Chardon Rd., Suite 110
Willoughby Hills, OH 44094 (USA)

Contact Person: Philip Ryder
CEO
440-832-0331
Phil@huneo.com

Date Prepared: December 17, 2025

Device Name:

Trade Name: WRAP System
Common Name: Ventilatory Effort Recorder
Classification Name: 21 CFR 868.2375, Breathing frequency monitor
Regulatory Class: 2
Product Code: MNR, OLV, OLZ

Predicate Device(s):

510(k) Number	Device Name	Type
K210593	Onera Sleep Test System (STS)	Predicate Device
K934599	(IL-PSG) Sandman	Predicate Device
K153412	Sleep Profiler	Predicate Device

Device Description:

The Wireless Realtime Attended Polysomnogram (WRAP) System is a wireless and wearable system for measuring (physiological) signals during a sleep study. The device can be used in a healthcare facility, clinical research environment, or the prescribed person's home, to perform the sleep study. The WRAP System consists of four sensors applied on the forehead, chest, lower leg, and finger area. The WRAP System measures biosignals from adult prescribed users including EEG, EOG, EMG, pulse oxyhemoglobin saturation, activity/ movement, acoustical signals, inertial measurement, and cannula for respiratory airflow. The WRAP System additionally captures ECG signals from the chest, EMG signals from the leg, and SpO2 from the finger. The four sensor assemblies are applied by the healthcare professional (HCP) to the user in the clinical setting, whereas the user applies the sensors in the home environment with remote support from the HCP. The device is not a life supporting physiological monitor.

Indications for Use:

The Wireless Realtime Attended Polysomnogram (WRAP) System measures and records multiple physiological parameters from a patient during a sleep study and its autoscoring algorithm scores sleep stages automatically. These recorded physiological parameters are used by clinicians to assist in evaluating the diagnosis of sleep disorders. The WRAP System is intended to be used on a patient, who has been prescribed a sleep study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but may be applied by a layperson. The recorded data will be made available to a healthcare professional to assist in the diagnosis of sleep disorders. The device is intended to be used for adults.

Substantial Equivalence:

A side-by-side comparison between WRAP System and the predicate devices is provided in the below Table 1.

Table 1) WRAP System & Predicate Comparative Analysis

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Device Manufacturer	Huneo, LLC	Onera B.V.	Melville Software Ltd.	Advanced Brain Monitoring, Inc.	NA
510(k) Clearance	TBD	K210593	K934599	K153412	NA
Product Code(s)	MNR, OLV, OLZ	MNR, OLV	OLV	OLZ	Sum of predicates' product codes are equivalent to subject device
Classification	Class II	Class II	Class II	Class II	Identical
FDA Regulation	868.2375	868.2375	882.1400	882.1400	Identical to Primary Predicate

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Indications for Use	The Wireless Realtime Attended Polysomnogram (WRAP) System measures and records multiple physiological parameters from a patient during a sleep study and its autoscoring algorithm scores sleep stages automatically. These recorded physiological parameters are used by clinicians to assist in evaluating the diagnosis of sleep disorders. The WRAP System is intended to be used on a patient, who has been prescribed a sleep study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but may be applied by a layperson. The recorded data will be made available to a healthcare professional to assist in the diagnosis of sleep disorders. The device is intended to be used for adults.	Onera STS measures and records multiple physiological parameters from a patient during a sleep study which are used by clinicians to make a decision on the diagnosis of sleep disorders. Onera STS is intended to be used on a patient, who has been prescribed a sleep study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but applied by a layperson. The recorded data will be made available to a healthcare professional to assist in the diagnosis of sleep disorders. The device is intended to be used for adults.	The SANDMAN provides paperless digital recording and handling of physiological signals intended for a sleep EEG laboratory.	Sleep Profiler is intended for use for the diagnostic evaluation by a physician to assess sleep quality and score sleep disordered breathing events in adults only. The Sleep Profiler is a software-only 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, snoring and sleep disordered breathing events (obstructive apneas, hypopneas and respiratory event related arousals). Central and mixed apneas can be manually marked within the records.	Similar to Primary Predicate regarding both measuring and recording multiple physiological parameters from a patient during a sleep study, Similar to Secondary Predicate IL-PSG Sandman regarding realtime monitoring capability and in-lab use, and Similar to Secondary Predicate Sleep Profiler regarding ability to score sleep stages automatically
Target Population	Adults	Adults	Adults	Adults	Identical

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Product Description	WRAP System is a wireless and wearable system for measuring (physiological) signals during a sleep study. The device can be used in a healthcare facility, clinical research environment, or the prescribed person's home, to perform the sleep study. The WRAP System consists of four sensors applied on the forehead, chest, lower leg, and finger area. The WRAP System measures biosignals from adult prescribed users including EEG, EOG, EMG, pulse oxyhemoglobin saturation, activity/ movement, acoustical signals, inertial measurement, and cannula for respiratory airflow. The WRAP System additionally captures ECG signals from the chest, EMG signals from the leg, and SpO2 from the finger. The four sensor assemblies are applied by the healthcare professional (HCP) to the user in the clinical setting, whereas the user applies the sensors in the home environment with remote support from the HCP. The device is not a life supporting physiological monitor.	Onera STS is a wearable system for measuring (physiological) signals during a sleep study. The device can be used in home (Home Healthcare Environment) as well as Professional Healthcare Facilities, to perform the sleep study. Onera STS consists of four sensors applied on the forehead, upper chest area, abdominal and lower leg area. The sensors measure EEG, EOG, EMG, ECG, bioimpedance based respiratory effort, bioimpedance based respiratory flow, cannula based respiratory flow, oxygen saturation, activity, position, and sound pressure level. The study preparation and data retrieval are done in a professional/ clinical environment by a dedicated trained operator. The device is not a life supporting physiological monitor.	Sandman device is used solely for the collection, storage and display of data collected by Sandman FDA cleared equipment that requires no modifications to support the function or input by qualified technologists.	The Sleep Profiler is a software application that analyzes previously recorded physiological signals obtained during sleep. The Sleep Profiler software can analyze any EDF files acquired with the Advanced Brain Monitoring X4 System and the X8 System models SP40 and SP29.	Substantially equivalent All performance testing did not raise new questions of safety and effectiveness as demonstrated through bench performance testing along with a clinical study.

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Use Environment	Home (data acquisition) Professional Healthcare Facility and Clinical Research Environment (data acquisition, analysis and reporting)	Home (Home Healthcare Environment) as well as Professional Healthcare Facilities	Professional Healthcare Facilities	Physician office (data analysis and reporting) No limitation on where data are acquired.	Similar to Primary Predicate for home use and all 4 devices for professional healthcare environment
Monitoring Parameters	EEG EOG EMG (Chin, Leg) SpO2 (Finger) ECG through chest patch Acoustical/air pressure Respiratory flow (via nasal cannula) Sound 6-axis IMU (accelerometer/ gyro)	EEG EOG EMG (Head, Leg) SpO2 (Forehead) ECG Respiratory effort (via bioimpedance) Respiratory flow (via nasal cannula) Sound pressure 3D accelerometer Activity (Chest)	Respiratory Effort (abdomen/chest) Airflow Pressure Snore Oximeter ECG EEG EMG EOG DC Leg Movement and other signals required for sleep studies	Software as a Medical Device (SaMD) scoring sleep stages (e.g., REM, N1, N2, N3, and Wake) and other events based on ABM's PSG recording equipment	Substantial Equivalent: Devices collect and measure (physiological) parameters during a sleep study.
Realtime Monitoring Capability	Yes	No	Yes	NA, no monitoring hardware, (SaMD)	Similar to Secondary Predicate IL-PSG Sandman
Telemedicine Capability	Yes	No	No	NA, SaMD	NA
Anatomical Sites	Forehead Chest Leg Finger	Forehead Chest Leg Abdomen,	Forehead Abdomen/Chest Leg Finger	NA, SaMD	Similar to Primary Predicate, except use of finger instead of abdomen Similar to Secondary Predicate IL-PSG Sandman, except use of abdomen/chest instead of solely chest

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Power Source (Energy)	Rechargeable Battery	Battery powered devices	Mains power connected	NA, SaMD	Similar to Primary Predicate
Materials (Skin Contacting)	Device materials are part of the device that touch the skin and found biocompatible	Patches are included with the device and found biocompatible	Unknown	NA, SaMD	Similar to Primary Predicate
Communication Interface	Bluetooth/ wireless to mobile device	Bluetooth/ wireless to the device	Wired	NA, SaMD	Similar to Primary Predicate
Duration of Use	Up to 16 hours	8 hours	8 hours/ overnight	NA, SaMD	Similar, both durations allow for intended use and were tested to these durations
Measured parameters	EEG (4 channels)	EEG (2 channels)	EEG (6 channels)	NA, SaMD	Similar, all have EEG channels and are acceptable for sleep study devices
	EOG (2 channels)	EOG (2 channels)	EOG (2 channels)	NA, SaMD	Identical, all have EOG channels
	EMG (2 channels), 2 locations	EMG (2 channels), 2 locations	EMG (3 channels), 3 locations	NA, SaMD	Identical to Primary Predicate. Secondary Predicate IL-PSG Sandman has an additional channel in a third location.
	SpO2 finger	Pulse oximeter capability (forehead)	SpO2 finger	NA, SaMD	Identical to Secondary Predicate IL-PSG Sandman. Different from Primary Predicate, which uses forehead for pulse oximetry
	ECG Chest Device[1] (single lead)	ECG (1 lead/channel)	ECG (single lead)	NA, SaMD	Similar, all include 1 channel ECG

[1] The subject device is not intended for the diagnosis of cardiac conditions, is not intended to be used with automated (algorithmic) cardiac analysis tools, and does not contain automated ECG analysis capabilities.

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
	Respiratory effort & respiratory flow via nasal cannula	Respiratory effort & Respiratory flow via nasal cannula	Respiratory effort & Nasal airflow and pressure	NA, SaMD	Similar, all use nasal cannula
	6-axis accelerometer/gyro and pitch and roll position	Position (1 channel derived from 3D accelerometer)	N/A	N/A, SaMD	Different, Primary Predicate only uses a derived parameter, and Secondary Predicate IL-PG Sandman does not have a position sensor
	Sound Power measurement	Sound Pressure	Snore-PTAF	N/A, SaMD	Similar to Primary Predicate
Sensor wiring	Electrodes are connected to Physical devices using wire leads.	Traces printed on a tape substrate and routed to a connector that connects the patches to their data collection modules.	Electrodes are connected to wire leads that are connected to a gear box	N/A, SaMD	Similar to Primary Predicate electrically, the Subject Device and Primary Predicate are identical in function. The Primary Predicate device employs single use patches with the built-in wire. The Subject Device uses reusable wired leads.
Attaching/ Wearing sensors/patches	Adhesive Tape	Adhesive Tape	Wires connected to a gear box that hangs on the patient's neck	N/A, SaMD	Similar to Primary Predicate
Sterility profiles	Clean but not sterile	Clean but not sterile	Clean but not sterile	NA, SaMD	Identical to Primary Predicate

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Biocompatibility	The device is considered as a surface device in contact with intact skin per ISO 10993-1. The biocompatibility evaluation was completed and included Cytotoxicity, Sensitization and Irritation testing. All testing passed.	The device is considered as a surface device in contact with intact skin per ISO 10993-1. The biocompatibility evaluation was completed and included Cytotoxicity, Sensitization and Irritation testing. All testing passed.	The device is considered as a surface device in contact with intact skin per ISO 10993-1. It is unknown if Sandman was in compliance to specific tests per ISO 10993-1.	NA, SaMD	Similar to Primary Predicate
Duration of Contact as per ISO 10993	Limited Exposure	Limited Exposure	Limited Exposure	NA, SaMD	Similar to Primary Predicate Onera and Secondary Predicate IL-PSG Sandman
Attachment to the Body	Electrodes, Foam and foam adhesive hydrogel Double-sided Tape – Double Coated Medical Polyethylene Tape Kinesiology Tape – high grade 100% cotton material with a 100% poly-acrylic adhesive Clear, transparent tape – thin, transparent polyurethane film	Onera uses four comfortable, patch-based sensors applied to the forehead, upper chest, abdominal area, and lower leg to record various physiological parameters during sleep. Specific materials that are in contact to the intact skin of subject are unknown.	Sandman utilizes various materials and sensors to record different physiological signals during a sleep study. Specific materials that are in contact with the intact skin of the subject are unknown.	NA, SaMD	Similar to Primary Predicate Onera and Secondary Predicate IL-PSG Sandman, all three use adhesive type materials to attach sensors/patches
Recording management	Complete control and visual feedback via Mobile App during the study and viewing within HHP	Unknown	Connected to a local computer. Visual feedback via computer display during the study	NA, SaMD	Similar to Secondary Predicate IL-PSG Sandman. Improved patient usability when compared to the IL-PSG Sandman.

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Signal amplification	Electrophysiological amplifiers for EEG, ECG, EOG, and EMG signals have a gain of approximately 385 times the raw signal. All other signals do not have any signal amplification.	Unknown	Unknown	NA, SaMD	Unknown, but expected to be similar to Secondary Predicate IL-PSG Sandman
Sampling frequencies	Meets American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated Events guidelines (Attachment_10_16_Troester)	Unknown	Meets American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated Events guidelines (Attachment_10_16_Troester)	NA, SaMD	Similar to Secondary Predicate IL-PSG Sandman
Automated Sleep Stage Scoring	Yes	No	No	Yes	Similar to Secondary Predicate Sleep Profiler
Autoscoring Algorithm Description	Automated algorithm that uses an AI model and categorizes each epoch as one of the defined sleep stages using a machine learning classifier.	NA	NA	Automated algorithm which spectrally decomposes the EEG signal, computes descriptors of sleep macro- and microstructure, and categorizes each epoch as one of the defined sleep stages	Similar to Secondary Predicate Sleep Profiler

Characteristic/ Feature	WRAP System (Subject Device)	Onera Sleep Test System (STS) (Primary Predicate)	IL-PSG Sandman (Secondary Predicate)	Sleep Profiler (Secondary Predicate)	Discussion of Differences
Autoscoring Algorithm Characteristics	Manager assigns a study to the autoscoring algorithm instead of a manual scorer and the algorithm is executed on the HHP Server in the cloud. The staging scoring results are available for viewing/editing within the WRAP System, just like manual scoring results.	NA	NA	Sleep Profiler will operate on any personal computer	Different: WRAP System autoscoring algorithm runs in the cloud while Secondary Predicate Sleep Profiler runs on a PC.

The technology to obtain sleep scoring capability is equivalent to that of the defined Predicate Device (K153412).

None of the indicated differences introduces new questions on safety or effectiveness.

Performance Data Summary:

Performance testing on the WRAP System confirmed that the device conforms to the defined applicable requirements of the following standards:

- IEC 60601-1 Basic safety and essential performance
- IEC 60601-1-2 EMC
- IEC 60601-1-6 Usability
- IEC 60601-1-11 Home Healthcare
- IEC 80601-2-26 Basic safety and essential performance of electroencephalographs
- IEC 60601-2-27 Basic safety and essential performance of electrocardiographic monitoring equipment
- ISO 80601-2-61 Basic safety and essential performance of pulse oximeter equipment

The device was tested and demonstrated to be safe in the event of defibrillation.

Biocompatibility Testing

Biocompatibility assessment of the WRAP System was conducted per *ISO 10993-1:2018-08, Biological evaluation of medical devices - Part 1* and *FDA Guidance on the Use of International Standard ISO 10993-1* on the surface device components in contact with intact skin less than 24 hours. **Table 2: WRAP System Components Biocompatibility Summary**

provides a summary of the Biocompatibility results where all test results passed and were compliant for the applicable standard.

Table 2: WRAP System Components Biocompatibility Summary		
WRAP System Test Article	**Standard**	**Results**
WRAP System Components in Contact with Intact Skin	ISO 10993-10:2021	Compliant: There were no signs of sensitization observed in the guinea pigs treated with the test article. and is not considered to elicit contact dermal allergenicity.
WRAP System Electrode Components	ISO 10993-10:2010	Compliant: Under the conditions of this protocol, the results indicate that the test article did not elicit a sensitization response.
WRAP System Nasal Cannula Component	ISO 10993-10:2021	Safe for its intended use.
WRAP System Components in Contact with Intact Skin	ISO 10993-23:2021 & ISO 10993-10:2010	Complaint: Test articles meet the requirements of the Intracutaneous Test and the test article was considered a negligible irritant under the conditions of this test.
WRAP System Electrode Components	ISO 10993-10:2010	Compliant: The test sample extracts produced no evidence of irritation, and the test article was considered a negligible irritant under the conditions of this test.
WRAP System Nasal Cannula Component	ISO 10993-23:2021	Safe for its intended use.
WRAP System Components in Contact with Intact Skin	ISO 10993-5:2009	Compliant: Test articles are not considered to elicit a cytotoxic effect under the conditions employed.
WRAP System Electrode Components		Compliant: The test article was considered non-cytotoxic under the conditions of this test.
WRAP System Nasal Cannula Component		Safe for its intended use.

The WRAP System device was designed and tested under the following standards and guidelines:

- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1 2022 Medical devices – Part 1: Application of usability engineering to medical devices
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – FDA guidance issued September 27, 2023
- Content of Premarket Submissions for Device Software Functions – FDA guidance issued June 14, 2023

Clinical Study Summary:

Huneo performed a clinical study at one accredited sleep center to evaluate the accuracy and signal quality of the WRAP System in comparison with an FDA cleared in lab polysomnography (IL-PSG) system (K934599) to show alignment to its proposed intended use(s) in a clinical and home use setting. The study used both healthy individuals (N=16) and sleep disorder prescribed individuals (N=20), where half were males and half were females with 19.4% of the individuals having Fitzpatrick skin type of V-VI.

WRAP System to IL-PSG
Regarding the agreement between the WRAP System and the Matched-Montage IL-PSG Sandman (K934599) as the primary endpoint, the overall agreement of scored stages between the WRAP System and the matched-montage IL-PSG System and in-lab pulse oximeter (K052186) is 96.3%, which is statistically higher than the protocol requirement of at least 80% agreement, refer to **Table 3: Confusion matrix for agreement between the WRAP System and IL-PSG (n=36)**. The one-proportion Z-test was statistically significant, supporting that the proportion of agreement is above 80% ($Z=67.65$; $p<0.0001$).

Table 3: Confusion matrix for agreement between the WRAP System and IL-PSG (n=36)

		Montage-Matched IL-PSG					
		Wake	**REM**	**N1**	**N2**	**N3**	**Total**
WRAP	**Wake**	**9,854**	233	57	351	97	**10,592**
	REM	11	**2,615**	10	15	0	**2,651**
	N1	20	5	**616**	**7**	**0**	**648**
	N2	77	37	21	**10,381**	64	**10,580**
	N3	0	0	0	2	**3,089**	**3,091**
	Total	9,962	2,890	704	10,756	3,250	**27,562**

WRAP System Finger Pulse Oximeter Accuracy
To validate the accuracy of the Huneo finger pulse oximeter sensor, a study was performed using 11 healthy non-smoking individuals of age 24-42 (6 males and 5 females, and 3 dark skin individual with Fitzpatrick V or VI) at the UCSF Hypoxia Lab, in accordance with ISO 80601-2-61:2019 201.12.1.101.2 and Annex EE.2, as recommended by the *FDA Guidance: Pulse Oximeters –Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff, March 2013*. The Huneo finger pulse oximeter results showed an accuracy (i.e., Arms) of ±3.15% in the range 70- 100%, which is within the accuracy specification for a reflectance sensor type recommended in *Pulse Oximeters –Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff, March 2013*.

WRAP System Manual Scoring to WRAP System autoscoring
The overall agreement between the WRAP System manual scoring and WRAP System autoscoring across all observations (N=30,604) was 83.6% (**Table 4: Confusion matrix for agreement between WRAP manual scoring and WRAP autoscoring (n=36)**). Cohen's Kappa also indicated substantial agreement with a Kappa value of 0.795. The one-proportion Z was

statistically significant, supporting that the proportion of agreement is above the protocol requirement.

Table 4: Confusion matrix for agreement between WRAP manual scoring and WRAP autoscoring (n=36)

		WRAP System Autoscoring					
		Wake	**REM**	**N1**	**N2**	**N3**	**Total**
WRAP System Manual	**Wake**	**10,495**	46	107	382	0	11,030
	REM	661	**1,964**	78	330	4	3,037
	N1	369	16	**336**	234	0	955
	N2	520	120	207	**11,546**	75	12,468
	N3	57	1	7	1,796	**1,253**	3,114
	Total	12,102	2,147	735	14,288	1,332	**30,604**

The predicate (Sleep Profiler, K153412) has an overall percent agreement of 73% with the confusion matrix shown (**Table 5: Confusion Matrix for Sleep Profiler (K153412) from Its FDA Summary**).

Table 5: Confusion Matrix for Sleep Profiler (K153412) from Its FDA Summary

		Epochs assigned by Sleep Profiler					
	Overall	Wake	N1	N2	N3	REM	Total
Epochs assigned by Expert Scoring	Wake	5449	950	567	45	413	7424
	N1	564	431	600	44	113	1752
	N2	582	801	9673	1408	118	12582
	N3	34	19	1035	3591	25	4704
	REM	194	221	550	1	2783	3749
	No-Cons	378	220	325	46	181	1150
	Total	7201	2642	12750	5135	3633	31361

Table 6: Device Performance Comparison compares device performance across stages and shows that the WRAP System autoscoring algorithm and Sleep Profiler performances are substantially equivalent.

Table 6: Device Performance Comparison

	WRAP System Autoscoring		**Sleep Profiler (K153412)**	
Stage	**% Positive Agreement**	**% Negative Agreement**	**% Positive Agreement**	**% Negative Agreement**
Wake	96%	98%	73%	94%
N1	35%	96%	25%	93%
N2	93%	98%	77%	84%
N3	40%	94%	76%	94%
REM	65%	93%	74%	97%
Overall	84%	N/A	73%	N/A

Substantial Equivalence Conclusion:

WRAP System is substantially equivalent to the predicates 1) Onera Sleep Test System (STS) (K210593), 2) IL-PSG Sandman (K934599) and 3) Sleep Profiler (K153412) in terms of intended use and overall technical characteristics, with autoscoring capability supported by Sleep Profiler (K153412). All performance testing did not raise new questions of safety and effectiveness as demonstrated through bench performance testing along with a clinical study. Based on the information provided in this 510(k), Huneo LLC concludes that the Subject device WRAP System is substantially equivalent to the predicate devices identified in this submission and as safe and effective.