July 15, 2024

Huxley Medical
℅ Grace Powers
Founder/ Principal Consultant
Powers Regulatory Consulting
2451 Cumberland Parkway SE
Suite 3740
Atlanta, Georgia 30339

Re: K240285
Trade/Device Name: Huxley SANSA Home Sleep Apnea Test (1000-00)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: June 11, 2024
Received: June 11, 2024

Dear Grace Powers:

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.

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,

Ting Song -S

for
Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K240285

Device Name
Huxley SANSA Home Sleep Apnea Test (1000-00)

Indications for Use *(Describe)*
The Huxley Home Sleep Apnea Test (SANSA) is a wearable device intended for use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The device is intended for the clinical and home use setting under the direction of a Healthcare Professional (HCP).

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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HUXLEY™ MEDICAL

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Huxley Medical Traditional 510(k) premarket notification.

Sponsor: Huxley Medical, Inc.
1465 Northside Dr NW Ste 217
Atlanta, GA, 30318
info@huxleymed.com

Submission Contact: Grace Powers, MS, MBA, RAC
Founder/Principal Consultant
Powers Regulatory Consulting
grace@powersregulatory.com

Submission Date: June 11, 2024

Subject Device: Trade Name: Huxley SANSA Home Sleep Apnea Test (1000-00)
Common Name: Ventilatory Effort Recorder
Classification Name: Breathing Frequency Monitor
Regulation: 21 CFR §868.2375
Regulatory Classification: Class 2
Product Code: MNR

Predicate Device:

Reference Devices: ANNE Sleep (K220095)
BioBeat Platform, BB-613WP Patch (K212153)
Wesper Lab (K203343)
WatchPAT ONE (K183559)

Device Description

The Huxley Home Sleep Apnea Test (SANSA™) is a wearable device intended for use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The device is intended for clinical and home use setting under the direction of a Healthcare Professional (HCP). The system is prescription use only.

The SANSA HSAT collects multiple physiological signals using a single wearable patch worn on the chest. The SANSA device contains a reflective PPG sensor, a single-lead ECG sensor, and a 3-axis accelerometer. The signals from these sensors are passed into a cloud-based algorithm which utilizes a combination of signal processing and AI/ML components to compute time-series data for clinician review and summary metrics for report output. The device outputs the following time-series channels: Oximetry, Heart Rate, Chest Movement, Snoring, Body Position, Respiratory Effort, Actigraphy, Sleep staging (Sleep/Wake), and ECG (reference channel only). The following summary metrics are calculated: sansa-Apnea Hypopnea Index (sAHI) and Total Sleep Time (TST).

Recorded data are uploaded to a software portal where physiological tracings are made available for be used for diagnostic purposes and is not intended by any automated ECG analysis system or algorithm.

review and event editing by a qualified healthcare professional. The device is intended to be worn for 10 hours per study. The ECG channel is intended to be used as a reference channel and is not intended to be used for diagnostic purposes and is not intended by any automated ECG analysis system or algorithm.

Intended Use/Indications for Use

The Huxley Home Sleep Apnea Test (SANSA™) is a wearable device intended for use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The device is intended for the clinical and home use setting under the direction of a Healthcare Professional (HCP).

An overview comparison of the SANSA HSAT (subject device) to the predicate and reference devices is presented in the table below.

Table 1: Device Comparison

Device Comparison	Subject Device: SANSA HSAT - K240285	Predicate Device: ANNE Sleep K220095	Reference Device (listed for specific technical characteristics)	Comparison
Manufacturer	Huxley Medical, Inc.	Sibel, Inc.	N/A	N/A
FDA Product Code	MNR	MNR	N/A	Identical
Regulation	868.2375	868.2375	N/A	Identical
Classification	II	II	N/A	Identical
Classification Name	Ventilatory Effort Recorder	Ventilatory Effort Recorder	N/A	Identical
Advisory Committee	Anesthesiology	Anesthesiology	N/A	Identical
Prescription Use?	Yes	Yes	N/A	Identical
Indications for Use	The SANSA Home Sleep Apnea Test (SANSA HSAT) is a wearable device intended for use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The device is intended for the clinical and/or home use setting under the direction of a Healthcare Professional (HCP).	Anne Sleep is a wearable sensor system intended for use in the collection, analysis, display, and storage of physiological parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for use in the clinical and home setting under the direction and interpretation by a Healthcare Professional (HCP).	N/A	Similar- The subject and predicate device have similar indications for use. Both are used to aid in the evaluation of sleep-related breathing disorders.

Device Comparison	Subject Device: SANSA HSAT – K240285	Predicate Device: ANNE Sleep K220095	Reference Device (listed for specific technical characteristics)	Comparison
Target Population	Adults (22 years age and older)	22 years age and older	N/A	Identical
Intended Use Environment	Clinics and Home Use	Recording in the home environment with the report and interpretation performed in the clinical setting.	N/A	Similar- The subject and predicate devices are both able to be used at home. The subject device can also be used in the clinical setting. Both the device's data are interpreted by clinicians.
Device Placement for Data Collection	Chest sensor	Chest and finger sensors	BioBeat platform, BB-613WP Patch K212153: Chest Sensor	Similar- Devices utilize chest sensors. Chest placement to collect oximetry is supported by the reference device.
Device Sensors	Chest Sensor Accelerometer ECG Reflectance Photo-plethysmography	Limb sensor Chest sensor Accelerometer ECG Photo- plethysmography	BioBeat platform, BB-613WP Patch K212153: Reflectance Photo-plethysmography	Similar- The subject and predicate device both use accelerometer, ECG, and photoplethysmography (PPG) sensors.
Channels	Oximetry Heart rate Chest movement Snoring Body position Respiratory effort Actigraphy Sleep stage (Sleep/Wake) ECG (Reference channel only)	Oximetry Heart rate Chest movement Snoring Body position Pulse rate Peripheral arterial tonometry (PAT)	Wesper (K203343) relevant channel: Respiratory Effort WatchPAT One (K183559) relevant channel: Actigraphy Sleep stage (Sleep/Wake)	Substantially equivalent: Each of the channels from the subject device is provided by the predicate and / or reference devices.

Device Comparison	Subject Device: SANSA HSAT – K240285	Predicate Device: ANNE Sleep K220095	Reference Device (listed for specific technical characteristics)	Comparison
Analysis Outputs	sAHI Body Position Discrete States Heart Rate Total Sleep Time SpO2	Sibel-AHI (based on manual scoring of data by HCP) Body Position Discrete States Heart Rate Total Sleep Time SpO2	N/A	Substantially equivalent: The subject device provides similar analysis to the predicate device.
Performance	Heart Rate: Arms ≤ 3 bpm (range 30-250 bpm) SpO2: Arms ≤ 3% (range 70-100%) Aid to Diagnosis of Moderate to Severe OSA (AHI≥15): Sensitivity 88.2%, Specificity 87.3%	Pulse Rate: 30-300 bpm ± 3 bpm Heart Rate: 30-300 bpm ± the greater of ±10% or ±5 bpm SpO2: Arms ≤ 3% (range 70-100%) Aid to Diagnosis of Moderate to Severe OSA (AHI≥15): Sensitivity 90%, Specificity 98%	BioBeat platform, BB-613WP Patch K212153: Arms HR: ±3%, HR Range: 40-250 bpm	Substantially equivalent: The subject device provides similar performance to the predicate device. The subject device does not report Pulse Rate. The predicate device diagnostic performance is between manual scoring by HCP of Sibel and PSG data, whereas the subject device utilizes an autoscored algorithm with no overread and correction. Similar diagnostic performance is achieved with comparable HSAT devices utilizing autoscore algorithms.

Device Comparison	Subject Device: SANSA HSAT– K240285	Predicate Device: ANNE Sleep K220095	Reference Device (listed for specific technical characteristics)	Comparison
Data Collection and Transfer	Patient data is physically transferred via USB after study conclusion.	Patient data is wirelessly transferred via Bluetooth from the sensors to a mobile phone. Data is then wirelessly transferred from the phone to the cloud when connected to the internet.	N/A	Similar: The subject device and predicate device both transfer patient data from the device to a cloud-based software platform for analysis. The subject device utilizes wired data transfer, whereas the predicate device utilizes wireless transfer, but this difference does not impact safety or effectiveness.
Recording Capacity	Approx. 10 hours per study. 2 nights of study maximum.	36 hours of continuous use	WatchPAT One (K183559): Approx. 10 hours	Substantially equivalent: The subject device and predicate device can both operate over a full night of sleep. Duration differences do not influence safety or effectiveness.
Energy Source	Rechargeable Lithium Polymer Battery	Rechargeable Lithium Polymer Battery	N/A	Identical
Analysis Software	Analysis performed off the recording device, on a compatible cloud-based software platform.	Analysis performed off the recording device, on a compatible cloud-based software platform.	N/A	Identical

Non-Clinical Performance Data
The subject devices was subject to non-clinical performance testing. There are no device-specific guidance documents, special controls document, and/or requirements in a device-specific regulation that are applicable to the subject device.

A list of the non-clinical bench testing is listed below:

- Heart Rate Testing and accuracy per 60601-2-47
- SPO2 Clinical and SQI Testing
- Body Position Testing
- Snoring Testing
- Actigraphy Testing
- Chest Movement Testing
- Respiratory Effort Testing
- Disposable ECG Electrodes Testing per ANSI/AAMI EC12 (Labeling, Biological Response, Adhesive performance duration of use, Packaging and shelf life, and the following electrical performance tests: AC impedance, DC offset voltage, combined offset instability and internal noise, and bias current tolerance).
- Usability Testing (Patients and Healthcare Providers) leveraging the following:
    - "Guidance for Industry and Food and Drug Administration Saff: Applying Human Factors and Usability Engineering to Medical Devices" issued February 3, 2016
    - IEC 62366-1, Medical Devices – Part 1: Application of usability engineering to medical devices
    - IEC 60601-1-6, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
    - IEC 60601-1-11, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- Software Verification testing including unit level and integration Testing in accordance with IEC 62304, Medical device software - Software life cycle processes and "Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Device Software Functions" issued June 14, 2023.
- Cybersecurity Testing in accordance with "Guidance for Industry and Food and Drug Administration Staff: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued September 27, 2023.
- EMC and Electrical Safety Testing per 60601-1, 60601-1-2, 60601-1-11, 60601-2-47 and 80601-2-61
- Cleaning, Disinfection and Shelf Life Testing

All non-clinical bench testing passed.

Biocompatibility Testing

The subject and predicate device are considered as surface devices in contact with intact skin per ISO 10993-1. The biocompatibility evaluation was completed and included Cytotoxicity, Sensitization and Intracutaneous Reactivity/Irritation testing. All testing passed.

Clinical Performance Data

SpO2 Accuracy: The Sansa device's SpO2 measurements were compared to arterial blood gas samples in healthy subjects over the range of 70-100% oxygen saturation according to Section 201.12.1 of ISO 80601-2-61 and Pulse Oximeters-Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff, Issued March 2013. The average root mean square error (A_{RMS}) met the required specifications of ≤ 3.5% for reflectance technology.

Subgroup	Category	Arms (70-100%)
Overall		2.4
Fitzpatrick	1-2	2.2
	3-4	3.7
	5-6	1.7
Sex	Male	2.4
	Female	2.4

Comparison to PSG: Sansa clinical performance was compared to the gold standard polysomnography (PSG) in a prospective multi-center clinical study in the United States (n = 533). Clinically acceptable performance between Sansa and PSG was demonstrated across all diagnostic conditions. The results of the study support that Sansa is sufficiently accurate as an aid to diagnose moderate to severe SDB. The study was demographically representative of patients with SDB across age, sex, race, ethnicity, BMI, and skin tone.

The Sansa device yielded the following diagnostic performance to diagnose moderate to severe SDB: Sensitivity of 88.2% (95% CI: 81.3, 93.2), Specificity of 87.3% (95% CI: 82.1, 91.5).

Subgroup analysis on race showed the following performance: White: Sensitivity of 88.1% (95% CI: 79.2, 94.1) and Specificity of 83.7% (95% CI: 76.7, 89.3); Black: Sensitivity of 86.8% (95% CI: 71.9, 95.6) and Specificity of 96.4% (95% CI: 87.5, 99.6); and All Other Races: Sensitivity of 100% (95% CI: 47.8, 100) and Specificity of 90.9% (95% CI: 58.7, 99.8). Subgroup analysis on Fitzpatrick score showed the following performance: 1-4: Sensitivity of 90.4% (95% CI: 83.5, 95.1) and Specificity of 87.4% (95% CI: 81.9, 91.8); 5-6: Sensitivity of 66.7% (95% CI: 34.9, 90.1) and Specificity of 86.4% (95% CI: 65.1, 97.1). Subgroup analysis on BMI (kg/m2) showed the following performance: ≤30: Sensitivity of 85.7% (95% CI: 69.7, 95.2) and Specificity of 90.3% (95% CI: 82.9, 95.2); >30: Sensitivity of 89.1% (95% CI: 80.9, 94.7) and Specificity of 84.5% (95% CI: 76.4, 90.7).

The Sansa device AI based Sleep/Wake classification algorithm was trained on 101 subjects and validated against the validation dataset (n=340 ITD) taken from gold standard scored PSG data. This validated classification resulted in a performance of Sensitivity (Sleep): 95% (95% CI: 95, 95) and Specificity (Sleep): 63% (95% CI: 62, 64).

Conclusion

The SANSA HSAT is substantially equivalent to the legally marketed predicate device as demonstrated by the similar indication for use, similar technologies and performance data, and does not raise different questions of safety and effectiveness.