January 28, 2025

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

Re: K244027
Trade/Device Name: SANSA HSAT
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: MNR
Dated: December 29, 2024
Received: December 30, 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.

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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

510(k) Number *(if known)*
K244027

Device Name
SANSA HSAT

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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.
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Atlanta, GA, 30318
info@huxleymed.com

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

Submission Date: December 27, 2024

Subject Device: Trade Name: SANSA HSAT
Common Name: Ventilatory Effort Recorder
Classification Name: Breathing Frequency
Monitor Regulation: 21 CFR §868.2375
Regulatory Classification: Class 2
Product Code: MNR

Predicate Device: SANSA HSAT (K240285)

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 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 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).

Comparison between Subject and Predicate Device

The purpose of this Special 510(k) submission is to activate the cellular capability of the SANSA HSAT (subject device). This is a change to the manufacturer's (Huxley Medical) own previously cleared device (K240285). There is no change to the Indications for Use, physical hardware of the device, principles of operation, device offerings, manufacturing process or device packaging as part of the cellular update.

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

Table 1: Device Comparison

Device Comparison	Predicate Device: SANSA HSAT (K240285)	Subject Device: SANSA HSAT	Comparison
Manufacturer	Huxley Medical, Inc.	Huxley Medical, Inc.	Identical
FDA Product Code	MNR	MNR	Identical
Regulation	868.2375	868.2375	Identical
Classification	II	II	Identical
Classification Name	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Identical
Advisory Committee	Anesthesiology	Anesthesiology	Identical
Prescription Use?	Yes	Yes	Identical
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).	The Huxley Home Sleep Apnea Test (SANSA™ Cellular) 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).	Identical
Target Population	Adults (22 years age and older)	Adults (22 years age and older)	Identical
Intended Use Environment	Clinics and Home Use	Clinics and Home Use	Identical

Device Placement for Data Collection	Chest sensor	Chest sensor	Identical
Device Sensors	Chest Sensor Accelerometer ECG	Chest Sensor Accelerometer ECG	Identical
	Reflectance Photo-plethysmography	Reflectance Photo-plethysmography	
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 Respiratory effort Actigraphy Sleep stage (Sleep/Wake) ECG (Reference channel only)	Identical
Analysis Outputs	sAHI Body Position Discrete States Heart Rate Total Sleep Time SpO2	sAHI Body Position Discrete States Heart Rate Total Sleep Time SpO2	Identical
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%	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%	Identical
Data Collection and Transfer	Patient data is physically transferred via USB after study conclusion.	Patient data is wirelessly transferred via Cellular (LTE-M) at the conclusion of the study. In the event of no connectivity or failed transfer, patient data is physically transferred via USB after study conclusion.	Similar – Cellular connectivity addition does not impact use, safety, or effectiveness of the device.
Recording Capacity	Approx. 10 hours per study. 2 nights of study maximum.	Approx. 10 hours per study. 2 nights of study maximum.	Identical
Energy Source	Rechargeable Lithium Polymer Battery	Rechargeable Lithium Polymer Battery	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.	Identical

Non-Clinical Performance Data

The following non-clinical testing was conducted to support device changes:

- Software Unit & Integration Testing to test firmware, and Software Verification Testing at the system level to verify the end-to-end functionality. This testing verified the additional features, ensuring that no regression occurred, and that the data integrity was not altered in the upload process
    - Testing was conducted 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 Controls Verification to verify the additional cybersecurity controls added to mitigate cybersecurity risks in cellular upload.
    - 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.
- Wireless Testing per FCC 47 CFR Part 15 Conducted and Radiated emissions, Part 24 and Part 27 Spurious Emissions, and SAR Testing per FCC 47 CFR Part 2.
    - No coexistence testing was conducted as it was not required in accordance with AAMI TIR 69, given the negligible risk tier of the device.

Conclusion

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