



December 10, 2025

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

Re: K252497  
Trade/Device Name: SANSA HSAT  
Regulation Number: 21 CFR 868.2375  
Regulation Name: Breathing Frequency Monitor  
Regulatory Class: Class II  
Product Code: MNR  
Dated: August 8, 2025  
Received: November 12, 2025

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Binoy J.  
Mathews -S**

Digitally signed by  
Binoy J. Mathews -S  
Date: 2025.12.10  
16:43:25 -05'00'

For

Rachana Visaria  
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

## Indications for Use

510(k) Number (if known)  
K252497

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.

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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.  
1465 Northside Dr NW Ste 217  
Atlanta, GA, 30318  
[info@huxleymed.com](mailto:info@huxleymed.com)

**Submission Contact:** Grace Powers, MS, MBA, RAC  
Founder/Principal Consultant  
Powers Regulatory Consulting  
[grace@powersregulatory.com](mailto:grace@powersregulatory.com)  
404-931-8730

**Submission Date:** August 8, 2025

**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:** Huxley Medical SANSa HSAT (K244027)  
**Reference Device:** 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 (Wake, REM, Non-REM), ECG (reference only). The following summary metrics are calculated: SANSa-Apnea Hypopnea Index (sAHI), SANSa Apnea Hypopnea Index – Central (sAHIC), Sleep Times (Total Sleep Time, Total REM Time, Non-REM sleep time) and AHI during REM.

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Recorded data is 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 subject SANSa HSAT device consists of the same physical device components, intended use case, and operation, as the predicate SANSa HSAT device cleared under K244027. This submission updates the algorithm to update performance and add the ability to classify between Obstructive and Central Sleep Apnea events using an AI/ML classifier and present a summary metric, SANSa Apnea Hypopnea Index – Central (sAHIC). REM/NREM Classification and REM related sleep metrics were also added.

**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 device and reference device are presented in the table below.

**Predicate and Reference Device**

The changes to the predicate device are limited to the updated performance, and addition of REM/Non-REM classifier and Central/Obstructive sleep apnea event classifier. These additions are supported by the legally marketed reference device WatchPat One (K183559).

**Table 1: Device Comparison**

Device Comparison	Predicate Device: SANSa HSAT (K244027)	Subject Device: SANSa HSAT	Reference Device WatchPAT One (K183559)	Comparison
<b>Manufacturer</b>	Huxley Medical, Inc.	Huxley Medical, Inc.	Itamar Medical	Identical
<b>FDA Product Code</b>	MNR	MNR	MNR	Identical
<b>Regulation</b>	868.2375	868.2375	868.2375	Identical
<b>Classification</b>	II	II	II	Identical
<b>Classification Name</b>	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Identical
<b>Advisory Committee</b>	Anesthesiology	Anesthesiology	Anesthesiology	Identical
<b>Prescription Use?</b>	Yes	Yes	Yes	Identical
<b>Indications for Use</b>	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	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	The WatchPAT™ ONE (WP1) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP1 is a diagnostic aid for the detection of	Identical to Predicate

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	<p>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).</p>	<p>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).</p>	<p>sleep related breathing disorders, sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake), snoring level and body position. The WP1 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), ApneaHypopnea index ("PAHI"), Central Apnea-Hypopnea index ("PAHic"), PAT sleep staging identification (PSTAGES) and snoring level and body position discrete states from an external integrated snoring and body position sensor. The WP1's PSTAGES and snoring level and body position provide supplemental information to its PRDI/PAHI/PAHic. The WP1's PSTAGES and snoring level and body position are 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. PAHic is indicated for use in patients 17 years and older. All other parameters are indicated for 12 years and older.</p>	
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<b>Target Population</b>	Adults (22 years age and older)	Adults (22 years age and older)	17 years and older (PAHlc) 12 years and older (all other parameters)	Identical to predicate
<b>Intended Use Environment</b>	Clinics and Home Use	Clinics and Home Use	Clinics and Home Use	Identical to predicate
<b>Device Placement for Data Collection</b>	Chest sensor	Chest sensor	Wrist, Chest	Identical to predicate. Reference device uses similar chest placement for detecting central sleep breathing disturbances.
<b>Device Sensors</b>	Chest Sensor Accelerometer ECG Reflectance Photo-plethysmography	Chest Sensor Accelerometer ECG Reflectance Photo-plethysmography	Chest Sensor Accelerometer Reflectance Photo-plethysmography	Identical  Similar to Reference device with same sensors and placement of chest sensor.
<b>Channels</b>	Oximetry Heart rate Chest movement Snoring Body position Respiratory effort Actigraphy ECG (Reference channel only)	Oximetry Heart rate Chest movement Snoring Body position Respiratory effort Actigraphy ECG (Reference channel only)	Oximetry Pulse rate Chest movement Snoring Body position Actigraphy Peripheral Arterial Tonometry	Identical to predicate.
<b>Analysis Outputs</b>	sAHI Body Position Discrete States Heart Rate Total Sleep Time SpO2  Sleep stage (Sleep/Wake)	sAHI sAHIc Body Position Discrete States Heart Rate Total Sleep Time SpO2  Sleep stage (Wake, REM, NREM)	pAHI pAHIc pRDI Body Position Discrete States Total Sleep Time SpO2  Sleep stage (pStages – Wake, Deep, Light, REM)	Identical outputs to predicate except for the addition of Sleep Stages and sAHIc.  Sleep staging is substantially equivalent to the reference device.
<b>Performance :</b>	Heart Rate: Arms $\leq 3$	Heart Rate: Arms $\leq 3$	Pulse Rate: 30-150 $\pm 1$	Identical

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<b>HR and SPO2</b>	bpm (range 30-250 bpm) SpO2 Arms $\leq$ 3% (range 70-100%)	bpm (range 30-250 bpm) SpO2 Arms $\leq$ 3% (range 70-100%)	bpm SpO2 Arms $\leq$ 3% (range 70-100%)	
<b>Performance: Central Detection</b>	N/A	sAHlc performance Sensitivity: 100% Specificity: 98.7%	pAHlc Performance Sensitivity: 71.4% Specificity: 98.6%	AHlc is substantially equivalent to the pAHlc output of the reference device.
<b>Data Collection and Transfer</b>	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.	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.	Patient data is transferred via Bluetooth	Identical to predicate
<b>Recording Capacity</b>	Approx. 10 hours per study. 2 nights of study maximum.	Approx. 10 hours per study. 2 nights of study maximum.	Approx. 10 hours	Identical to predicate
<b>Energy Source</b>	Rechargeable Lithium Polymer Battery	Rechargeable Lithium Polymer Battery	One OTS 1.5V Alkaline AAA Battery	Identical to predicate
<b>Analysis Software</b>	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.	Analysis performed off the recording device, on a compatible cloud-based software platform.	Identical to predicate

**Non-Clinical Performance Data**

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

- Software testing was used to verify that the metrics are calculated correctly and to verify the outputs of the AI/ML classifiers.
- Benchtop performance testing was used to verify the updated chest movement.
- A regression analysis of the SPO2 was performed against the performance test data collections to show no substantial difference in PPG signal processing.

No further system or performance testing was required.

**Clinical Performance Data**

The performance of AHlc and NREM/REM sleep classification were compared to the PSG reference standard in a multisite in-lab comparison study with 325. The patient population was 48% (n=156) Male, 52% (n=169) Female, 68.6% (n=223) White, 26.8% (n=87) Black/African American, 5 subjects were Asian, 1 American Indian / Alaskan Native, and 9 subjects Other race. The majority of subjects (95.7%, n=311) were non-

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Hispanic. Ages ranged from 18-87 years old with average age of 55.4 years old. The severity was normal for 34% of subjects, mild for 29%, moderate for 17% and severe for 21% using AHI-4% with cutoffs of 5 events/h (mild), 15 events/h (moderate), and 30 (severe) events/h. Twelve (12) subjects were scored positive on the reference PSG for central sleep apnea using a cutoff of  $\geq 10$  central events / hour. The sAHIc performance of the SANSa device met the pre-specified endpoints for Sensitivity and Specificity as compared to PSG AHIc. The sensitivity of the Sansa device to detect AHIc  $\geq 10$  was 100.0% (95% CI 73.5, 100.0) and the specificity was 98.7% (95% CI 96.8, 99.7).

The sensitivity and specificity of REM/NREM epoch level classification measured by Sansa against PSG was 74.6% (95% CI 73.6%, 75.6%) and 89.5% (95% CI 89.2%, 89.8%), respectively.

**Conclusion**

The SANSa System is substantially equivalent to the legally marketed predicate device as demonstrated by the same intended use and similar technologies. The addition of sAHIc summary metric and additional sleep staging with REM and NREM stages are supported by use in the reference device, WatchPAT ONE, and do not raise questions of safety and effectiveness compared to the predicate and reference devices.