October 29, 2025

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

Re: K250882
Trade/Device Name: SANSA HSAT
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, BZQ, MWJ
Dated: September 26, 2025
Received: September 30, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250882

Please provide the device trade name(s).

SANSA HSAT

Please provide your Indications for Use below.

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 and cardiac 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 system is prescription use only.

The SANSA device records and stores ECG recording for up to 10 hours of wear time which can be displayed in the software portal for manual annotation and analysis. The SANSA does not provide automated analysis of the ECG and is not intended to be used with a 3rd party automated algorithm and is not intended for pacemaker analysis.

Please select the types of uses (select one or both, as applicable).

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

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
404-931-8730

Submission Date: March 24, 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, BZQ, MWJ

Predicate Device: iRhythm Zio Monitor (K202359)
Reference Device: Huxley Medical SANSA HSAT (K244027)

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™ device records and stores ECG recording for up to 10 hours of wear time which can be displayed in the software portal for manual annotation and analysis. The SANSA™ does not provide automated analysis of the ECG and is not intended to be used with a 3rd party automated algorithm and is not intended for pacemaker analysis.

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. 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.

Intended Use/Indications for Use

The Huxley Home Sleep Apnea Test (SANSA^{TM}) 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 and cardiac 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 system is prescription use only.

The SANSA device records and stores ECG recording for up to 10 hours of wear time which can be displayed in the software portal for manual annotation and analysis. The SANSA does not provide automated analysis of the ECG and is not intended to be used with a 3rd party automated algorithm and is not intended for pacemaker analysis.

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

Table 1: Device Comparison

Device Comparison	Subject Device: SANSA HSAT	Predicate Device: Zio Monitor (K202359)	Reference Device: SANSA HSAT (K244027)	Comparison
Manufacturer	Huxley Medical, Inc.	iRhythm Technologies, Inc	Huxley Medical, Inc.	Identical to reference device.
FDA Product Codes	MNR, BZQ, MWJ	DSH, MWJ	MNR, BZQ	Identical to reference device with the addition of MWJ from the predicate device.
Primary Regulation	868.2375	870.2800	868.2375	Identical to reference device.
Classification	II	II	II	Identical to reference device.
Classification Name	Ventilatory Effort Recorder	Medical magnetic tape recorder	Ventilatory Effort Recorder	Identical to reference device.
Advisory Committee	Anesthesiology	Cardiovascular	Anesthesiology	Identical to reference device.
Prescription Use?	Yes	Yes	Yes	Identical
Indications for Use	The Huxley Home Sleep Apnea Test (SANSA^{TM}) is a	The Zio Monitor is a prescription-only, single-patient-use,	The Huxley Home Sleep Apnea Test (SANSA^{TM}) is a	Equivalent - The addition of ECG monitoring

Device Comparison	Subject Device: SANSA HSAT	Predicate Device: Zio Monitor (K202359)	Reference Device: SANSA HSAT (K244027)	Comparison
	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 system is prescription use only. The SANSA™ device records and stores ECG recording for up to 10 hours of wear time which can be displayed in the software portal for manual annotation and analysis. The SANSA™ does not provide automated analysis of the ECG and is not intended to be used with a 3rd party automated algorithm and is not intended for pacemaker analysis.	ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue or anxiety.	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).	capability for manual annotation and analysis of the ECG signal with no automated ECG analysis is supported by the indication for use of the predicate device.
Target Population	Adults (22 years age and older)	18 years and older	Adults (22 years age and older)	Identical to reference device.
Intended Use	Clinics and Home	Clinics and Home	Clinics and Home	Identical

Device Comparison	Subject Device: SANSA HSAT	Predicate Device: Zio Monitor (K202359)	Reference Device: SANSA HSAT (K244027)	Comparison
Environment	Use	Use	Use	
Device Placement for Data Collection	Chest sensor	Chest Sensor	Chest sensor	Identical
Device Sensors	Chest Sensor Accelerometer ECG Reflectance Photo-plethysmography	ECG	Chest Sensor Accelerometer ECG Reflectance Photo-plethysmography	Equivalent - Subject and Predicate contain ECG.
Channels	Oximetry Heart rate Chest movement Snoring Body position Respiratory effort Actigraphy Sleep stage (Sleep/Wake) ECG	ECG	Oximetry Heart rate Chest movement Snoring Body position Respiratory effort Actigraphy Sleep stage (Sleep/Wake) ECG (Reference channel only)	Equivalent – Official ECG channel (not reference only) is equivalent to the ECG channel of the reference device.
ECG Recording Characteristics	Number of Leads: Single Lead ECG Lead Orientation: Modified Lead II ECG A/D Sampling Rate: 250 Hz ECG Resolution:	Number of Leads: Single Lead ECG Lead Orientation: Modified Lead II ECG A/D Sampling Rate: 200 Hz ECG Resolution:	Number of Leads: Single Lead ECG Lead Orientation: Modified Lead II ECG A/D Sampling Rate: 250 Hz ECG Resolution:	Identical to reference device. Equivalent to predicate device in performance in recording capability and lead orientation. Higher sample rate in subject device does not raise questions of safety or effectiveness with predicate device as the output ECG is

Device Comparison	Subject Device: SANSA HSAT	Predicate Device: Zio Monitor (K202359)	Reference Device: SANSA HSAT (K244027)	Comparison
	15.5 bits	15.5 bits	15.5 bits	equivalent.
Analysis Outputs	sAHI Body Position Discrete States Heart Rate Total Sleep Time SpO2	No analysis provided by device.	sAHI Body Position Discrete States Heart Rate Total Sleep Time SpO2	Identical to reference device. Subject device and predicate device lack ECG analysis output.
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% ECG Recording Accuracy: • Frequency Response: 0.67 Hz to 40 Hz • Input Impedance: >10 MΩ • Gain Accuracy: Maximum amplitude error ±10%	No Heart Rate Analysis Does not collect SpO2 Does not diagnose OSA ECG Recording Accuracy: • Frequency Response: 0.67 Hz to 40 Hz • Input Impedance: >10 MΩ • Gain Accuracy: Maximum amplitude error ±10% • Gain Stability: <3% over a 24-hour period	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% ECG Recording Accuracy: • Frequency Response: 0.67 Hz to 40 Hz • Input Impedance: >10 MΩ • Gain Accuracy: Maximum amplitude error ±10%	Identical to reference device. Identical ECG recording accuracy to predicate device.

Device Comparison	Subject Device: SANSA HSAT	Predicate Device: Zio Monitor (K202359)	Reference Device: SANSA HSAT (K244027)	Comparison
	• Gain Stability: <3% over a 24-hour period • Timing Accuracy: <30 seconds	• Timing Accuracy: <30 seconds	• Gain Stability: <3% over a 24-hour period • Timing Accuracy: <30 seconds	
Data Collection and Transfer	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 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.	Identical to reference device.
Recording Capacity	Approx. 10 hours per study. 2 nights of study maximum.	Continuous recording for 14 days.	Approx. 10 hours per study. 2 nights of study maximum.	Identical to reference device. Predicate device is focused on 14 days of data and subject and reference are focused on sleep.
Energy Source	Rechargeable Lithium Polymer Battery	Lithium Manganese Dioxide Coin Cell	Rechargeable Lithium Polymer Battery	Identical to reference device.
Analysis Software	Analysis performed off the recording device, on a compatible cloud-based software platform. No automated ECG analysis conducted.	No ECG analysis provided by the device.	Analysis performed off the recording device, on a compatible cloud-based software platform. No automated ECG analysis conducted.	Identical to reference device. Equivalent to predicate.

Non-Clinical Performance Data

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

- Software Unit & Integration Testing to test portal functionality. This testing verified the additional features, and that the data integrity was not altered in the EDF or PDF export process.
- The following performance testing verifies the accuracy of the SANSA device's ECG recording:
    - Testing to FDA recognized consensus standard IEC 60601-2-47 Ed. 2.0 (2012-02) Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
        - ECG recorder performance testing (Retested with latest device firmware)
        - Database Accuracy testing for beat detection and heart rate (testing leveraged from previous clearance due to lack of changes)
    - Testing to FDA recognized consensus standard ANSI AAMI EC12:2000/(R)2015 Disposable ECG electrodes (testing leveraged from previous clearance due to lack of changes)
        - ECG electrode performance testing
        - On-body adhesive performance testing
- Human Factors Usability Testing conducted on patients and clinicians in accordance with FDA Guidance Document "Applying Human Factors and Usability Engineering to Medical Devices" Issued February 3, 2016. (Testing leveraged from previous clearance due to lack of changes)

No further system or performance testing was required, as all updates made were isolated in cloud software functionality.

Clinical Performance Data

Sansa ECG clinical performance was validated through comparison to a simultaneously collected reference standard Holter monitor. Clinically acceptable performance was demonstrated through qualitative and quantitative analysis of the ECG signal.

Conclusion

The SANSA System is substantially equivalent to the legally marketed predicate device as demonstrated by the similar intended use and similar technologies, with the reference device leveraged to address the sleep-disordered breathing indications for use. The addition to the indications for use to allow usage of the existing ECG waveform for diagnostic purposes is supported by the predicate device. The updates made to the subject device in this submission do not raise questions of safety and effectiveness compared to the predicate and reference devices.