June 22, 2026

VivaQuant, Inc. DBA Rhythm Express
% Kathy Herzog
Sr. Regulatory, Quality, and Compliance Consultant
DuVal & Associates, P.A.
1820 Medical Arts Building
825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K253148
Trade/Device Name: RX-1 Sleep
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: May 13, 2026
Received: May 13, 2026

Dear Kathy Herzog:

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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.06.22 13:11:12 -04'00'

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

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)*
K253148

Device Name
RX-1 Sleep

Indications for Use *(Describe)*
RX-1 Sleep is a Software as a Medical Device (SaMD) to aid in the evaluation of sleep-related breathing disorders in adults suspected of having sleep apnea. RX-1 Sleep is a cloud-based algorithm that analyzes inputs provided by two FDA cleared devices intended for clinical and home use: a) the Rhythm Express RX-1 mini and b) a Viatom pulse oximeter. Biophysical parameters provided by RX-1 Sleep are recorded and stored for presentation to a Healthcare Professional (HCP). RX-1 Sleep is intended for use under the direction of a Healthcare Professional.

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.

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K253148
510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

VivaQuant Inc. d.b.a. Rhythm Express
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Arden Hills, MN 55112

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Correspondent Contact: Kathy Herzog, DuVal & Associates, P.A.
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herzog@duvalfdalaw.com

Date Prepared: May 12, 2026

II. DEVICE

Name of Device:	RX-1 Sleep
Classification Name:	Breathing Frequency Monitor
Regulation:	868.2375
Common or Usual Name:	Ventilatory Effort Recorder
Device Panel:	
Regulatory Class:	Class 2
Product Code:	MNR

III. PREDICATE AND REFERENCE DEVICES

Predicate device: Huxley SANSA Home Sleep Apnea Test (K244027). This predicate device has not been subject to a design-related recall.

Reference device: NightOwl (K213463).

IV. DEVICE DESCRIPTION

RX-1 Sleep is a Software as a Medical Device (SaMD) that measures the apnea–hypopnea index (AHI), sleep/wake, posture and respiratory effort. RX-1 Sleep is indicated for patients suspected of having sleep apnea. RX-1 Sleep employs two cloud-based static/locked AI deep learning models for AHI and for sleep/wake that receive inputs from two FDA-cleared devices used in the clinical and home environment: a) the Rhythm Express RX-1 *mini* Remote Cardiac Monitoring System (RCMS) (K241179), and b) a Viatom pulse oximeter

(K191088). Additionally, RX-1 Sleep includes two non-AI device software functions (DSFs) that rely on inputs from the RX-1 *mini* and use traditional signal processing techniques for respiratory effort estimation and posture detection during sleep. These non-AI-DSFs do not interact with the AI-DSFs.

The RX-1 *mini* is worn on the chest and communicates ECG and heart rhythm information, as well as actigraphy from an on-board triaxial accelerometer to the RS-1 cloud-based server via a cellular or Wi-Fi connection. The pulse oximeter is worn as indicated and records functional oxygen saturation of arterial hemoglobin (SpO2) while the patient is asleep. Pulse oximetry data are communicated to the RX-1 *mini* via a secure Bluetooth link for upload of SpO2 data to the RS-1 server and all data are synchronized. RX-1 Sleep resides on the RS-1 Server and outputs a consolidated sleep report, accessible via the RX-1 *mini* Clinic Portal. The Operator Portal presents RX-1 Sleep outputs and full disclosure signals for review by a qualified healthcare professional.

V. INDICATIONS FOR USE

RX-1 Sleep is a Software as a Medical Device (SaMD) to aid in the evaluation of sleep-related breathing disorders in adults suspected of having sleep apnea. RX-1 Sleep is a cloud-based algorithm that analyzes inputs provided by two FDA cleared devices intended for clinical and home use: a) the Rhythm Express RX-1 *mini* and b) a Viatom pulse oximeter. Biophysical parameters provided by RX-1 Sleep are recorded and stored for presentation to a Healthcare Professional (HCP). RX-1 Sleep is intended for use under the direction of a Healthcare Professional.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate device analyze ECG, accelerometer, and oximetry data from external wearable sensors and use an AI algorithm to analyze apnea severity in accordance with AASM guidelines. The minor differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness, as presented in the table below. The overall performance of the RX-1 Sleep algorithm reflects algorithmic refinement within the same clinical application that does not alter the clinical meaning of the output or change how the device is used in patient management.

Table 1: Subject vs. Predicate Device Technological Characteristics Comparison

Characteristic	Subject Device (K253148)	Predicate Device (K244027)	Reference Device K213463	Comparison
Manufacturer	VivaQuant, Inc.	Huxley Medical	Ectosense NV	NA
Product code	MNR	MNR	MNR	Identical
Classification	II	II	II	Identical
Common name	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Ventilatory Effort Recorder	Identical
Advisory committee	Anesthesiology	Anesthesiology	Anesthesiology	Identical
Prescription use	Yes	Yes	Yes	Identical

Characteristic	Subject Device (K253148)	Predicate Device (K244027)	Reference Device K213463	Comparison
Indications for use	RX-1 Sleep is a Software as a Medical Device (SaMD) to aid in the evaluation of sleep-related breathing disorders in adults suspected of sleep apnea. RX-1 Sleep is a cloud-based algorithm that analyzes inputs provided by two FDA cleared devices intended for clinical and home use: a) the Rhythm Express RX-1 *mini* and b) a Viatom pulse oximeter. Biophysical parameters provided by RX-1 Sleep are recorded and stored for presentation to a Healthcare Professional (HCP). RX-1 Sleep is intended for use under the direction of a Healthcare Professional.	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).	The NightOwl is a wearable device intended for use in the recording, analysis, displaying, exporting, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adult patients suspected of sleep apnea. The device is intended for the clinical and home setting use under the direction of a Healthcare Professional (HCP).	Equivalent; the devices are all intended to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea. The devices are used in the home or clinical setting and record, store, and analyze biophysical inputs from wearable sensors.
Target population	Adults (22 years age and older)	Adults (22 years age and older)	Adults (22 years age and older)	Identical
Intended use environment	Clinic and Home Use	Clinic and Home Use	Clinic and Home Use	Identical
System architecture	Sleep apnea algorithm and two wearable sensors	Sleep apnea algorithm and a single wearable with multiple sensors	Sleep apnea algorithm and a single wearable with multiple sensors	Equivalent; the devices all use proprietary analysis software to analyze data from wearable sensors.
Data source and sensors	Proprietary chest worn ECG monitor with triaxial accelerometer (RX-1	Proprietary chest-worn sensor that includes ECG monitor with triaxial	Optical plethysmography sensor, accelerometer	Equivalent; the devices all use external, wearable sensors

Characteristic	Subject Device (K253148)	Predicate Device (K244027)	Reference Device K213463	Comparison
	mini). Pulse oximeter with finger sensor that employs transmissive photoplethysmography (PPG) with dual-wavelength (660 and 940 nm) optical sensors to measure SpO_2.	accelerometer and pulse oximeter that employs reflectance photoplethysmography (PPG) with wavelengths range from 600 to 1000 nm optical sensors to measure SpO_2.		that record key parameters as input to evaluate sleep disordered breathing.
Analysis	Analysis performed on a compatible cloud-based software platform	Analysis performed on a compatible cloud-based software platform	Analysis performed on a compatible cloud-based software platform	Equivalent
Outputs	**RX-1 Sleep Analysis Outputs**: AHI Sleep/wake Total sleep time Posture Respiratory effort **Pass-through Outputs from RX-1 *mini*** Heart rate Arrhythmias Activity (optional) SpO2	**SANSA HSAT Analysis Outputs**: AHI Sleep/wake Total sleep time Posture Respiratory effort Activity Snoring Chest movement ECG (reference channel only) SpO2	**Night Owl Analysis Outputs:** pAHI calculation tuned to the AASM's '1A Rule' for the scoring of hypopnea pAHI calculation tuned to the AASM's '1B Rule' for the scoring of hypopnea	Equivalent; all devices report AHI as the primary output.
AI Algorithm AHI estimation	Static/locked deep learning model operating on ECG-derived and SpO_2 features, followed by deterministic post-processing	Heuristic rules-based algorithm using SpO_2 desaturation and cardio-respiratory cyclic pattern detection	Signal Processing Algorithm using PPG and accelerometer data.	Functionally equivalent; the device algorithms analyze physiological data inputs and outputs are validated against PSG studies to the same criteria.
Sleep/wake	Static/locked AI model operating on per-epoch ECG-based and SpO_2 features with fixed	AI classifier operating on actigraphy, heart rate, and HRV features	Estimated based on actigraphy and PPG features	Functionally equivalent; the AI models produce the same binary output that is

Characteristic	Subject Device (K253148)	Predicate Device (K244027)	Reference Device K213463	Comparison
	parameters			validated against PSG studies to the same criteria.
Respiratory effort	Non-AI processing of accelerometer and ECG-derived signals	Non-AI processing of PPG-derived signals	Not applicable.	Functionally equivalent for subject and predicate devices; the devices use non-AI signal processing of chest wall motion to analyze respiratory effort.
Posture	Non-AI computation from triaxial accelerometer data	Non-AI computation from triaxial accelerometer data	Not applicable.	Equivalent for subject and predicate devices.
AHI Performance	Aid to Diagnosis of: (a) **Mild to Moderate to Severe Sleep Apnea** (AHI ≥ 5): Sensitivity 87.80%, 95% CI [83.05, 91.62%] Specificity 93.91%, 95% CI [90.00, 96.63%] (b) **Moderate to Severe Sleep Apnea** (AHI≥15): Sensitivity 88.54%, 95% CI [80.42, 94.14%] Specificity 95.79%, 95% CI [93.25, 97.57%] (c) **Severe Sleep Apnea** (AHI≥30): Sensitivity 88.24%, 95% CI [72.55, 96.70%] Specificity 97.51%, 95% CI [95.59, 98.75%]	Aid to Diagnosis of: **Moderate to Severe Sleep Apnea** (AHI≥15): Sensitivity 88.2%, 95% CI [81.3, 93.2%] Specificity 87.3%, 95% CI [82.1, 91.5%]	Aid to Diagnosis of: (a) **Mild to Moderate to Severe Sleep Apnea** (AHI ≥ 5): Sensitivity 100% Specificity 82.3% (b) **Moderate to Severe Sleep Apnea** (AHI≥15): Sensitivity 97.3% Specificity 88.6% (c) **Severe Sleep Apnea** (AHI≥30): Sensitivity 84.0% Specificity 97.9%	Functionally equivalent; AHI results are validated against PSG studies using the same criteria for all devices.

Characteristic	Subject Device (K253148)	Predicate Device (K244027)	Reference Device K213463	Comparison
	Bland–Altman results (Rule 1B): Bias: 0.08, 95% CI [-0.31, 0.47] events/hr Lower LoA: −8.49, 95% CI [-9.17, -7.82] events/hr Upper LoA: +8.65, 95% CI [7.98, 9.33] events/hr			
Sleep/wake	**Sleep/wake performance**: Sensitivity: 91.63%, 95% CI [91.54, 91.72%] Specificity: 83.34%, 95% CI [83.12, 83.56%]	**Sleep/wake performance**: Sensitivity: 95.0%, 95% CI [94.8-95.1%] Specificity: 62.7%, 95% CI [61.9-63.5%]	Not applicable	Similar; the subject and predicate devices have similar sensitivity (>90%) and the subject device has improved specificity which improves AHI computation accuracy.
Data communication	Cellular or Wi-Fi	Cellular or USB	Bluetooth	Similar; the devices use verified electronic interfaces for data upload.
Maximum Sleep Study Duration	No limitation on hours/night. Up to 30 night maximum.	Approx. 10 hours per study. 2 night maximum.	Battery powered by coin cell	Similar; both the subject and predicate devices allow for monitoring of multiple nights of sleep.

VII. PERFORMANCE DATA

Non-Clinical Performance Data

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.

The following standards and FDA guidances were used to support verification and validation testing, risk management, and labeling development:

- FDA guidance "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices" issued Sept. 6, 2017

- FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" issued February 3, 2016
- ANSI AMMI ISO 14971:2019 Medical devices – Applications of risk management to medical devices
- AAMI TIR 57:2016 Principles for medical device security – Risk management
- AAMI TIR 97:2019 Principles for medical device security – Postmarket risk management for device manufacturers
- AAMI CR 34971:2022 Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1
- ISO 15223-1 Fourth edition 2021-07 Medical devices – Symbols to be used with information to be supplied by the manufacturer: Part 1: General requirements

RX-1 Sleep Testing
Software verification testing was completed in alignment with the following standards and FDA guidances:

- IEC 82304-1 Edition 1.0 2016-10 Health software – Part 1: General requirements for product safety
- ANSI AAMI IEC 62304:2006/A1:2106 Medical device software – Software life cycle processes [including Amendment 1 (2016)]
- AAMI TIR 36:2007 Validation of software for regulated processes
- FDA guidance "Content of Premarket Submissions for Device Software Functions" issued June 14, 2023
- FDA draft guidance "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations" issued January 7, 2025
- FDA guidance "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration", issued February 3, 2026
- FDA guidance "Off-the-Shelf Software Use in Medical Devices", issued August 11, 2023.

Clinical Performance Data
VivaQuant RX-1 Sleep clinical performance was evaluated against gold-standard polysomnography (PSG) using data from the Stanford Technology Analytics and Genomics in Sleep (STAGES) study to establish clinical validity and performance. The VIVA-STAGES study was a prospective, multi-center, cross-sectional investigation of sleep disorders conducted in the United States. All subjects underwent overnight polysomnographic (PSG) recordings. PSG studies were manually scored by certified independent sleep technologists under both Rule 1A and Rule 1B in accordance with the American Academy of Sleep Medicine (AASM) guidelines for scoring of sleep and associated events (version 3).

The results of the VIVA-STAGES study provide prospective performance validation of RX-1 Sleep and classification of sleep apnea severity from physiological signals (ECG and SpO_2) on 476 PSG studies. The study was demographically representative of patients with sleep disorders across age, sex, race, and BMI. The study cohort (n = 476) had a median age of 47 years (25th percentile = 36 years, 75th percentile = 57 years), with eligibility restricted to 21-85 years. The

cohort was 52.3% male (n = 249) and 47.7% female (n = 227). By BMI, 21.0% (n = 100) of subjects were normal weight (BMI ≤ 25), 34.2% (n = 163) were overweight (BMI 25–30), and 44.7% (n = 213) were obese (BMI > 30). By race, the cohort consisted of (78.6%, n = 374) White/Caucasian, with 5.3% (n = 25) Black/African-American and 16.2% (n = 77) identifying as another race.

The primary endpoint evaluated agreement between RX-1 Sleep predicted AHI and PSG-scored AHI under AASM Rule 1B using Bland–Altman analysis. Bland–Altman analysis showed minimal bias (0.08) and narrow limits of agreement (LoA) (−8.49 to 8.65), well within the predefined acceptance criterion, indicating good agreement between methods. The results are summarized in Table 2a (for Rule 1B) and Table 2b (for Rule 1A).

The powered secondary endpoints evaluated the sensitivity and specificity of RX-1 Sleep for detecting AHI ≥ 5 under Rule 1B. The diagnostic performance to diagnose mild sleep apnea yielded sensitivity of 87.8% (95% CI: 83.1–91.6%) and specificity of 93.9% (95% CI: 90.0–96.6%). The results are summarized in Table 3.

The descriptive secondary endpoints evaluated the sensitivity and specificity of RX-1 Sleep for detecting AHI ≥ 15 under Rule 1A and 1B and AHI >= 5 under Rule 1A. The results are summarized in Table 4.

Additional endpoints evaluated sensitivity and specificity at the severe OSA threshold (AHI ≥ 30) under Rule 1A and 1B, and sleep/wake classification. The results are summarized in Table 5 and Table 6 .

The results of this analysis confirmed that RX-1 Sleep was sufficiently accurate as an aid to diagnose mild (AHI >= 5) to moderate (AHI>=15) to severe (AHI>=30) sleep apnea and to identify sleep/wake epochs. The key results are provided in Tables 2a and 2b (Bland-Altman agreement), Table 3 (AHI > 5), Table 4 (AHI > 15), Table 5 (AHI > 30), and Table 6 (Sleep/Wake detection).

Table 2a: Bland Altman Analysis - Primary Endpoint Rule 1B

Statistic	Study Population (N=476)
Bias (mean difference)	0.08
SD of differences	4.37
Lower LoA	−8.49
Upper LoA	8.65
Success (LoA within prespecified limits)	**Yes**

Table 2b: Bland Altman Analysis - Rule 1A

Statistic	Study Population (N=476)
Bias (mean difference)	−0.36
SD of differences	6.98
Lower LoA	−14.04
Upper LoA	13.33

Table 3: AHI at Threshold of *AHI ≥ 5*

Desaturation	Sensitivity (95% CI)	Specificity (95% CI)
3%	86.63% (82.67%, 89.97%)	81.20% (72.93%, 87.82%)
4%	87.80% (83.05%, 91.62%)	93.91% (90.00%, 96.63%)

Table 4: AHI at threshold of *AHI ≥ 15*

Desaturation	Sensitivity (95% CI)	Specificity (95% CI)
3%	85.79% (79.88%, 90.50%)	89.08% (84.93%, 92.41%)
4%	88.54% (80.42%, 94.14%)	95.79% (93.25%, 97.57%)

Table 5: AHI at threshold of *AHI ≥ 30*

Desaturation	Sensitivity (95% CI)	Specificity (95% CI)
3%	83.54% (73.51%, 90.94%)	97.48% (95.42%, 98.79%)
4%	88.24% (72.55%, 96.70%)	97.51% (95.59%, 98.75%)

Table 6: Sleep/Wake Detection

Category	Sensitivity (95% CI)	Specificity (95% CI)
Sleep (AT)	91.63% (91.54%, 91.72%)	83.34% (83.12%, 83.56%)

Posture and respiratory effort endpoints were analyzed in a prospective multi-center clinical study in the United States (n = 30) in comparison to the PSG reported posture and respiratory effort.

The results of the prospective analysis confirm that RX-1 Sleep is sufficiently accurate to discriminate posture and estimate respiratory effort. The key results for posture and respiratory effort are provided in Table 7 and 8, respectively.

Table 7: Posture Performance, RX-1 Sleep

Population	Accuracy
ITT for posture endpoint (n=17)	94.7% (94.6-94.8)
AT for posture endpoint (n=13)	94.2% (94.2-94.3)

Table 8: Respiratory Effort Performance, RX-1 Sleep

Population	Accuracy
ITT for respiration endpoint (n=27)	89.1% (88.5-89.8)
AT for respiration endpoint (n=22)	89.4% (88.7-90.1)

The clinical performance results demonstrated that RX-1 Sleep is able to accurately measure AHI, detect sleep, posture and respiratory effort and the device meets prespecified performance specifications.

VIII. CONCLUSIONS

The subject RX-1 Sleep SaMD has the same intended use as the predicate Huxley SANSA HSAT device (K244027) to analyze physiological signals collected during sleep to aid in the evaluation of sleep-related breathing disorders. Both devices analyze ECG, accelerometer, and oximetry data from external wearable sensors and employ AI-based algorithm to analyze apnea-hypopnea severity with functionally equivalent results. The minor differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. Clinical and software testing demonstrated that RX-1 Sleep accurately classifies mild to moderate and moderate to severe AHI based on inputs from the RX-1 *mini* and the Viatom pulse oximeter, accurately distinguishes sleep postures and identifies sleep and wake epochs, and evaluates respiratory effort during sleep. RX-1 Sleep performance was comparable to the performance of the predicate Huxley SANSA HSAT device relative to AHI and sleep/wake detection. The overall performance of the RX-1 Sleep algorithm as compared to the predicate device for moderate to severe AHI ($\geq$ 15) reflects algorithmic refinement within the same clinical application that does not alter the clinical meaning of the output or change how the device is used in patient management. The RX-1 Sleep algorithm also has acceptable AHI performance for mild to moderate and mild to moderate to severe AHI categories in comparison with the NightOwl reference device using the same validation criteria. Thus, the subject device is as safe and as effective as the predicate Huxley SANSA HSAT system, and meets FDA's criteria for substantial equivalence to the predicate device per 21 CFR § 807.100 (b)(2).