February 8, 2024

EnsoData
Sigrid Schoepel
Vice President Regulatory Affairs
10 E Doty St., Suite 449
Madison, Wisconsin 53703

Re: K231355
Trade/Device Name: Aurora
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR
Dated: January 10, 2024
Received: January 11, 2024

Dear Sigrid Schoepel:

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,

Rachana Visaria -S

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

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)*
K231355

Device Name
Aurora

Indications for Use *(Describe)*
Aurora is a Software as a Medical Device (SaMD) that establishes sleep quality. Aurora automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data collected during sleep using compatible devices. Aurora is intended for use by and by order of a healthcare professional to aid in the diagnosis of sleep disorders including sleep apnea in adults

The Aurora output, including automatically detected respiratory events and parameters, may be displayed and edited by a qualified healthcare professional. The Aurora output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

Aurora is not intended for use with polysomnography devices.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K231355 Aurora
Traditional 510(k) Summary
Prepared in accordance with the content and format outlined in 21 CFR 807.92

I. SUBMITTER

Name:	EnsoData, Inc.
Address:	10 E. Doty Street, Suite 449 Madison, WI 53703 USA
Phone:	(608)509-4704
Contact Person:	Sigrid Schoepel
Email:	sigrid@ensodata.com

Date: January 11, 2024

II. SUBJECT DEVICE INFORMATION

Trade Name:	Aurora
Common Name:	Automatic Event Detection Software for Sleep Device Signals
Classification Name:	21 CFR 868.2375 Breathing Frequency Monitor
Regulatory Class:	II
Product Code:	MNR

Intended Use:

Aurora is a Software as a Medical Device (SaMD) that establishes sleep quality. Aurora automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data collected during sleep using compatible devices. Aurora is intended for use by and by order of a healthcare professional to aid in the diagnosis of sleep disorders including sleep apnea in adults.

The Aurora output, including automatically detected respiratory events and parameters, may be displayed and edited by a qualified healthcare professional. The Aurora output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

Aurora is not intended for use with polysomnography devices.

III. PREDICATE DEVICE

Trade Name:	SleepImage System
Common Name:	Automatic Event Detection Software for Sleep Device Signals
Classification Name:	21 CFR 868.2375 Breathing Frequency Monitor
Regulatory Class:	II
Product Code:	MNR

510(k): K182618

IV. SUBJECT DEVICE DESCRIPTION

Aurora is a Class II Software as a Medical Device (SaMD), intended to aid in the evaluation of sleep disorders, where it may inform or drive clinical management. Aurora is a software application that is indicated for use on a general-purpose computing platform. It is a cloud-based software-as-a-medical-device (SaMD) with a user interface that runs in a web browser.

Aurora automatically analyzes and displays photoplethsmography (PPG) signal data including SPO2 and pulse/heart rate only from compatible FDA-cleared medical purpose pulse oximeters that meet Aurora's data acquisition requirements for sampling rate, digital resolution, measurement range, and accuracy range.

Following upload of a compatible PPG study to the cloud software, the algorithm functions by verifying minimum signal quality, study length, and technical adequacy requirements, preprocessing the data including normalization, digital filtration, and artifact detection/rejection procedures, applying machine learning algorithms including multiple deep neural network machine learning models, statistical signal processing analyses including time-domain and time-frequency domain analyses over multiple time and resolution scales, and other analyses. These analyses output a detected set of events and derived signals for the PPG study that are post-processed and logically filtered according to algorithm rules based on the American Academy of Sleep Medicine (AASM) recommended scoring event, desaturation, and association rules. Aurora algorithm outputs, including scored respiratory events, sleep stages, Aurora Apnea-Hypopnea Index (eAHI), Total Sleep Time (TST), Sleep Efficiency (SE), Sleep Latency (SL), Wake After Sleep Onset (WASO), and Oxygen Desaturation Events Index (ODI) measures, are stored and made available for display, editing, and review in Aurora by qualified healthcare professionals.

Aurora reports results of the automated data analysis based on AASM guidelines, including the Aurora output Apnea-Hypopnea Index (eAHI) and total sleep time (TST). The algorithm outputs are graphical and numerical displays and reports of sleep latency, sleep duration, sleep quality, and sleep pathologies including sleep disordered breathing. The Aurora displays and reports are for the use by or on the order of physicians, trained technicians, or other healthcare professionals to evaluate sleep disorders where it may inform or drive clinical management taking into consideration other factors that normally are considered for clinical management of sleep disorders for adults.

The clinician can view raw data for interpretation, edit events, write clinical notes, and customize sleep reports for the patient.

Aurora output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The table below compares the predicate device, "SleepImage System" with the subject device Aurora.

Element	**Predicate Device** **MyCardio, LLC dba SleepImage** **K182618** **SleepImage System**	**Subject Device** **EnsoData, Inc.** **K231355** **Aurora**	**Equivalency**
Indications for use	The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality. The SleepImage System analyzes, displays and summarizes Electrocardiogram (ECG) or Plethysmogram (PLETH) data, typically collected during sleep, that is intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders, where it may inform or drive clinical management for children, adolescents and adults. The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing. The SleepImage System output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional.	Aurora is a Software as a Medical Device (SaMD) that establishes sleep quality. Aurora automatically analyzes, displays, and summarizes Photoplethysmogram (PPG) data collected during sleep. Aurora is intended for use by and by order of a healthcare professional to aid in the diagnosis of sleep disorders including sleep apnea in adults. The Aurora output, including automatically detected respiratory events and parameters, may be displayed and edited by a qualified healthcare professional. The Aurora output is not intended to be interpreted or clinical action taken without consultation of a qualified healthcare professional. Aurora is not intended for use with polysomnography devices.	Similar
Intended Use	The SleepImage System is Software as a Medical Device (SaMD) that establishes sleep quality, intended for use by or on the order of a Healthcare Professional to aid in the evaluation of sleep disorders based on Electrocardiogram (ECG) or Plethysmogram (PLETH) recordings, typically collected during sleep.	Aurora is intended for use by and by order of a healthcare professional to aid in the diagnosis and evaluation of sleep disorders including sleep apnea, where it may inform or drive clinical management for adults.	Similar
Patient Population	Children, Adolescents and Adults	Adults	Similar Aurora operates on a subset of the population of SleepImage
Environment of Use	N/A (Software) (Clinicians use the device within their clinic to view and edit the automatically scored sleep tests)	N/A (Software) (Clinicians use the device within their clinic to view and edit the automatically scored sleep tests)	Same
Method of Access	General-purpose computing platform with internet connection	General-purpose computing platform with internet connection	Same

Element	Predicate Device **MyCardio, LLC dba SleepImage** **K182618** **SleepImage System**	Subject Device **EnsoData, Inc.** **K231355** **Aurora**	Equivalency
Principle of Operation	Cloud-based web application Software as a Medical Device (SaMD)	Cloud-based web application Software as a Medical Device (SaMD)	Same
Input Source	HSAT and PSG devices	EDF signal files from compatible FDA-cleared medical purpose pulse oximeters PPG devices	Similar Aurora uses a subset of the input sources
Signals Analyzed	ECG or PPG; with oximetry Without referencing a particular, or a list of particular, ECG [or PPG] signal sources or recording devices.	PPG and oximetry Aurora analyzes PPG and oximetry data for the purposes of sleep analysis and sleep disorder detection with compatible FDA-cleared medical purpose PPG and oximetry signal sources and recording devices. PPG and oximetry are recorded by a third-party PPG device, converted into EDF (European Data Format), and the EDF files are analyzed by the Aurora system.	Similar Aurora uses a subset of the predicate signals
Interoperable Data Format	EDF; ASCII	EDF	Similar
Output Parameters	Sleep duration (total sleep time), sleep latency, sleep efficiency, wake after sleep onset, sleep stages, sleep quality, fragmentation & periodicity, oxygen desaturation	Sleep duration (total sleep time), sleep latency, wake after sleep onset, sleep stages, sleep efficiency, duration and percentage of sleep and wake, oxygen saturation and desaturation	Similar
Analysis of Sleep-Disordered Breathing Events	The SleepImage Apnea Hypopnea Index (sAHI), presented when oximeter data is available, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing.	Automatic detection of sleep-disordered breathing events, for calculation of eAHI when both PPG and oximetry data are present, is intended to aid healthcare professionals in diagnosis and management of sleep disordered breathing.	Similar
Diagnostic Parameters	SQI, SAI, RDI, ODI, AHI (AHI, oAHI, cAHI), WASO, TST	Apnea-Hypopnea Index (eAHI), Total Sleep Time (TST), Sleep Efficiency (SE), Sleep Latency (SL), Wake After Sleep Onset (WASO), and Oxygen Desaturation Events Index (ODI)	Similar Aurora offers a subset of the predicate diagnostic parameters
Display of Analysis Results	Graphical and numerical presentations and reports	Graphical and numerical presentations and reports	Same
Edits and Corrections to Automatic Analysis	The clinician can view raw data for interpretation, adjust events, write clinical notes, and customize sleep reports for the patient. Clinicians may review and utilize the results to	The clinician can view raw data for interpretation, adjust events, write clinical notes, and customize sleep reports for the patient.	Same

Element	Predicate Device **MyCardio, LLC dba SleepImage** **K182618** **SleepImage System**	Subject Device **EnsoData, Inc.** **K231355** **Aurora**	Equivalency
	make recommendations for further testing, referral, and/or therapy.	Clinicians may review and utilize the results to make recommendations for further testing, referral, and/or therapy.	
Intended Users	Used by or on the order of physicians, trained technicians, or other healthcare professionals to evaluate sleep disorders where it may inform or drive clinical management taking into consideration other factors that normally are considered for clinical management of sleep disorders.	Used by or on the order of physicians, trained technicians, or other healthcare professionals to evaluate sleep disorders where it may inform or drive clinical management taking into consideration other factors that normally are considered for clinical management of sleep disorders.	Same
Cybersecurity	Use of secure authentication protocols Data is transferred between user's general-purpose computing platform and cloud- based server, utilizing secure authentication protocols over the Internet	Authentication controls, authorization controls, cryptographic controls, access controls, checksum controls, software distribution controls, intrusion detection system controls, network and systems controls, and database controls.	Same

VI. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination. Since this is a software-only medical device that does not control other devices the performance data do not include biocompatibility, electrical safety, electromagnetic compatibility, mechanical, acoustic, or animal testing.

The device was designed and tested under the following standards and guidelines:

- EN ISO 13485 Third Edition 2016/A11 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- IEC 62304 Edition 1.1 2015-06 Medical device software - Software life cycle processes
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions – FDA guidance issued September 27, 2023
- Content of Premarket Submissions for Device Software Functions – FDA guidance issued June 14, 2023

The primary metric for assessing performance of Aurora (subject device) is the Aurora Apnea Hypopnea Index (eAHI). The eAHI depends on the number of sleep disordered breathing events detected, normalized by a determination of total sleep time (TST), where the TST is the total amount of sleep time during the recording period.

The performance testing validated Aurora's determination of the eAHI on single channel photoplethysmography (PPG) and oximetry signals for adult patients. Supportive performance testing validated Aurora's determination of Wake, Light non-rapid eye movement (NREM), Deep NREM, and

REM Sleep, and performance metrics for TST; Sleep Efficiency (SE); Sleep Latency (SL); Wake After Sleep Onset (WASO); and Oxygen Desaturation Events Index (ODI).

Simultaneous polysomnography (PSG) and home sleep apnea test (HSAT) recordings were collected for adult patients (n=158) using Philips Respironics Sleepware G3 (K202142), Natus Sandman Elite (K153353), and Polysmith Sleep System (K161650) for PSG recordings, and Viatom Checkme O2 (K191088) for HSAT recordings. Each of the PSG recordings were manually scored by three registered polysomnographic technologists using AASM scoring guidelines following the 3% desaturation guidance. For an event to be officially scored or reported, a consensus of at least two-thirds among the scorers was required. Each PSG was reviewed by a board-certified sleep physician to provide clinical confirmation of scoring and technical adequacy.

Performance in terms of sensitivity and specificity was assessed at an AHI cut-off of AHI >= 5.

Apnea Hypopnea Index (eAHI vs sAHI)				
Device	Desaturation	Sample Size (n)	Sensitivity	Specificity
Aurora Subject K231355	3%	158	92.6% (87.2%, 97.2%)	71.6% (59.2%, 83.7%)
	4%	158	89.4% (81.6%, 96.1%)	76.8% (67.1%, 85.4%)
SleepImage Predicate K182618	Unspecified	189	98.7% (97.0%, 100%)	84.8% (72.6%, 97.1%)

Sleep Staging				
Device	Category	Sample Size (n)	Sensitivity	Specificity
Aurora Subject K231355	Wake	52,622	86.7% (86.5%, 87.0%)	93.5% (93.4%, 93.7%)
	Light Non-REM	69,438	80.9% (80.6%, 81.2%)	85.5% (85.2%, 85.7%)
	Deep Non-REM	10,195	63.4% (62.4%, 64.3%)	95.9% (95.7%, 96.0%)
	REM	14,459	83.6% (83.0%, 84.2%)	97.5% (97.4%, 97.5%)

Sleep Profile and Oxygen Saturation						
Device	Category	Deming Regression		Bland-Altman		
		Slope ß1	Intercept ß0	Mean Difference (MD)	Upper Limit (ULOA)	Lower Limit (LLOA)
Aurora Subject K231355	eAHI (3%) [events/hour]	0.936 (0.853, 1.033)	0.023 (-1.185, 1.122)	1.000 (0.630, 1.367)	14.575 (13.779, 15.363)	-12.574 (-13.371, -11.786)
	eAHI (4%) [events/hour]	0.982 (0.903, 1.130)	1.219 (0.116, 1.985)	-1.039 (-1.326, -0.749)	9.307 (8.692, 9.931)	-11.386 (-12.001, -10.763)
	Total Sleep Time [hours]	1.159 (1.035, 1.318)	-0.695 (-1.576, -0.005)	-0.093 (-0.132, -0.059)	1.145 (1.060, 1.216)	-1.330 (-1.414, -1.259)
	Sleep Efficiency [hours/hours]	1.154 (1.031, 1.317)	-0.088 (-0.205, 0.003)	-0.011 (-0.017, -0.007)	0.163 (0.151, 0.173)	-0.185 (-0.198, -0.176)
	Sleep Latency [hours]	1.114 (0.997, 1.290)	-0.023 (-0.185, 0.090)	-0.129 (-0.154, -0.089)	0.884 (0.831, 0.970)	-1.143 (-1.196, -1.057)
	Wake After Sleep Onset [hours]	1.073 (0.938, 1.219)	-0.271 (-0.436, -0.121)	0.167 (0.140, 0.196)	1.131 (1.073, 1.193)	-0.797 (-0.855, -0.735)
	Oxygen Desaturation Index [events/ hours]	0.962 (0.896, 1.056)	1.667 (0.330, 2.847)	-1.046 (-1.417, -0.677)	13.223 (12.426, 14.015)	-15.315 (-16.111, -14.522)

CONCLUSION

The subject device met objective performance goals for eAHI, staging, sleep profile, and saturation analysis of the compatible pulse oximeter device in comparison to the manually scored simultaneously collected PSG sleep tests. The subject device agreement with single-channel PPG is considered substantially equivalent to the predicate device and the subject device does not raise new or additional questions of safety and effectiveness.

VII. CONCLUSIONS

The subject device is similar in intended use and functionality to the predicate device. The subject device has the same technological characteristics and features as the predicate device and does not raise new questions of safety or effectiveness as demonstrated through the system design and testing. Software verification and validation, cybersecurity, and performance testing were conducted to confirm the device design met user needs and specifications and was acceptable to qualified users.

The conclusions drawn from the clinical and nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as the legally marketed predicate device.