September 21, 2022

Neumetry Medical Inc
Paul Chen
CEO
47102 Mission Falls Ct., Suite 210
Fremont, California 94539

Re: K221179
Trade/Device Name: SomnoMetry
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: August 22, 2022
Received: August 22, 2022

Dear Paul Chen:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K221179

Device Name

SomnoMetry (V 1.0)

Indications for Use *(Describe)*

SomnoMetry is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults only. SomnoMetry is a software-only medical device to be used to analyze physiological signals and automatically score sleep study results, including the staging of sleep, AHI, and detection of sleep-disordered breathing events including obstructive apneas. It is intended to be used under the supervision of a clinician in a clinical environment. All automatically scored events are subject to verification by a qualified clinician.

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.

510(K) Summary

Prepared in accordance with 21 CFR 807.92

1. Submitter

Name:	Neumetry Medical Inc.
Contact Person:	Paul Chen
	paul@neumetry.com
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	Fremont, CA -4539
Phone:	925 997 9560
Date:	September 19, 2022

2. Subject Device

Device Name:	SomnoMetry
Model Number:	V1.0
Common Name:	Automatic Event Detection Software for Polysomnograph With Electroencephalograph
Regulation Number:	21 CFR 882.1400
Regulation Name:	Electroencephalograph
Regulatory Class:	II
Product Code:	OLZ
Review Panel:	Neurology

3. Predicate Device

EnsoData Inc., EnsoSleep K162627

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. Device Description

The SomnoMetry is an Artificial Intelligent/Machine Learning (AI/ML)-enabled Software as a Medical Device (SaMD) that automatically scores sleep study results by analyzing polysomnography (PSG) signals recorded during sleep studies. It is intended to be used under the supervision of a clinician in clinical environments to aid in the diagnosis of sleep and respiratory related sleep disorders.

All scored events that are analyzed, displayed, and summarized can be manually marked or edited by a qualified clinician during review and verification.

The SomnoMetry SaMD employs a broad array of signal processing, data indexing, conventional machine learning and deep learning algorithms/approaches in PSG physiological signals to derive actionable clinical insights.

SomnoMetry consists of:

- A web Application Programing Interface (API) to allow authenticated users to upload PSG files to SomnoMetry Platform
- A database to store the input, intermedium output, final output, and associated data
- A database API to access the database and store/retrieve the output
- A dashboard to display, retrieve, manage, edit, verify, and summarize the output
- An AI/ML Engine using AI/ML algorithms/approaches to analyze PSG data
- A reporting API to generate sleep reports

SomnoMetry works in the following sequence:

- Upload PSG data via the upload API (SSL encrypted)
- Analyze PSG data with SomnoMetry AI/ML Engine
- The output of the AI/ML Engine is stored in the database
- The database API queries the database and retrieves output
- The output of SomnMetry can be reviewed, retrieved, managed, edited, and verified via the dashboard
- Generate sleep reports via the dashboard

5. Indications For Use

SomnoMetry is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults only. SomnoMetry is a software-only medical device to be used to analyze physiological signals and automatically score sleep study results, including the staging of sleep, AHI, and detection of sleep-disordered breathing events including obstructive apneas. It is intended to be used under the supervision of a clinician in a clinical environment. All automatically scored events are subject to verification by a qualified clinician.

6. Summary of Technological Characteristics

The SomnoMetry software employs a broad array of signal processing, data indexing, conventional machine learning and deep learning algorithms/approaches in PSG signals to score the sleep study results automatically which has similar intended use and indications for use as the predicate device. The main difference in the intended use is that the predicate and subject devices use different algorithms. The two devices have similar technological characteristics: both algorithms automatically process and score sleep staging and respiratory events, and both SomnoMetry's AI/ML and the predicate's automated algorithms have optimized to ensure the accuracy and precision in scoring. The AI/ML algorithms do not introduce any new risks or unexpected results. Clinical performance testing confirmed that the SomnoMetry's AI/ML

algorithms performances are substantially equivalent to those by the device predicate's automated algorithms.

Table 1: Technological Characteristics Comparison

Elements	**Predicate Device** EnsoSleep K162627	**Subject Device** SomnoMetry
Classification	OLZ, Automated Event Detection Software for Polysomnograph with Electroencephalograph	OLZ, Automated Event Detection Software for Polysomnograph with Electroencephalograph
Indications for use	EnsoSleep is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory related sleep disorders in adults only. EnsoSleep is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study results, including the staging of sleep, detection of arousals, leg movements, and sleep disordered breathing events including obstructive apneas. All automatically scored events are subject to verification by a qualified clinician. Central apneas, mixed apneas, and hypopneas must be manually marked within records.	SomnoMetry is intended for use for the diagnostic evaluation by a physician to assess sleep quality and as an aid for the diagnosis of sleep and respiratory-related sleep disorders in adults only. SomnoMetry is a software-only medical device to be used to analyze physiological signals and automatically score sleep study results, including the staging of sleep, AHI, and detection of sleep-disordered breathing events including obstructive apneas. It is intended to be used under the supervision of a clinician in a clinical environment. All automatically scored events are subject to verification by a qualified clinician.
Intended Use	Analyze pre-recorded physiological data acquired during sleep.	Analyze pre-recorded physiological data acquired during sleep and derive actionable clinical insights.
Patient population	Adults only	Adults only
Scoring rules	American Academy of Sleep Medicine scoring manual and guidelines.	American Academy of Sleep Medicine scoring manual and guidelines.
Environment of use	Physician office (data analysis and reporting). No limitation on where data are acquired.	Physician office. No limitation on where data are acquired.
Score sleep staging	Yes	Yes
Score sleep disorder	Yes	Yes

respiratory events		
Automatically initiates sleep study scoring	Yes	Yes
Algorithm description	Automated algorithms are applied to the raw signals in order to derive additional signals and interpret the raw and derived signal information.	A broad array of signal processing, data indexing, conventional machine learning and deep learning algorithms/approaches are applied to the raw signals to derive actionable clinical insights.
Physical Characteristics	Operates on any PC with Windows 7 and 8 operating system platforms.	Web-based software operates in the cloud with Windows, Mac OS, or Linux
Cybersecurity	Authentication controls, authorization controls, cryptographic controls, access controls, checksum controls, software distribution controls, intrusion detection system controls, network and systems controls, and database controls.	User authentication with strong password, authorization, end to end SSL encryption, access controls, checksum, network and database controls, intrusion prevention system, and anonymization.

7. Performance Data

Neumetry conducted the necessary non-clinical testing and clinical evaluations on the SomnoMetry with past results supporting the determination of substantial equivalence. Performance testing and activities that were conducted included the followings:

- Software verification and validation which included software code reviews, automated testing, acceptance testing and labeling review.
- Study that utilized retrospective clinical data to demonstrate automatic scoring sleep study results.
- Design traceability that confirms all requirement tracing is complete from design inputs to verification/validation and that all risk controls are implemented.
- Design verification testing which confirmed that all software requirements are developed as expected
- Design validation testing which simulated the intended use to confirm that the end-to-end functionality of the SomnoMetry in conjunction with the AI/ML algorithms meets the design requirements
- A cybersecurity and data security testing were conducted to verify that data and patient protected health information security measures are thoroughly included in the design of the software.

Non-clinical Testing

Safety and performance of the SomnoMetry have been verified and validated through software testing and analytical validation. Software development and testing were performed in

accordance with *"IEC 62304:2006/A1:2015, Medical Device Software – Software life cycle processes"*. Risk has been assessed in accordance with *"ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices"*. During software testing, all pre-defined acceptance criteria for the SomnoMetry were met and all software test cases passed. The same verification and validation methodology, risk assessment and acceptance criterion were used for predicate device.

Retrospective Clinical Performance Testing – Clinical Evaluation

The clinical evaluation was provided in this submission in accordance with *"Software as a Medical Device (SaMD): Clinical Evaluation - Guidance for Industry and Food and Drug Administration Staff"* (December 2017). The clinical evaluation included a total of 201 polysomnography (PSG) files obtained from 2 AASM accredited Sleep Testing Facilities in California as the ground truths to validate the SomnoMetry AI/ML algorithms.

An archived collection of retrospective diagnostic clinical PSG subject data was obtained from the 2 AASM Accredited Sleep Testing Facilities and were verified to meet the specified disease spectrum, medical condition, medication, and demographic requirements.

To construct the final study sample from the archived collection population, a randomized sampling with proportionate allocation across each sleep apnea disease severity quantile (normative, mild, moderate, and severe sleep apnea) and sleep cycles was used to construct a valid sample of N=201 adult subjects. Age of subjects from 20 to 84 was selected. No race/ethnicity information was collected in either AASM Accredited Sleep Test Facility.

SomnoMetry SaMD performance was evaluated across the following 2 experimental endpoints:

- Endpoint 1: As SomnoMetry is intended to assist clinicians with the assessment of sleep quality, therefore device performance for sleep staging scoring must be validated.
- Endpoint 2: As SomnoMetry is intended to assist clinicians with scoring sleep disordered respiratory events used in diagnostic evaluation, therefore device performance for diagnosing sleep apnea must be validated.

Table 2 confusion matrix with conditional probabilities shows that the performance of SomnoMetry is non-inferior compared to AASM gold standard of manually scored PSG data. The results confirm that clinical performance achieved by the SomnoMetry for sleep staging is substantially equivalent to the predicate device.

Table 2: Confusion Matrix

	W	1	2	3	R
Subjects #	**167**	**167**	**167**	**167**	**167**
Event #	**28789**	**5791**	**47881**	**12888**	**13733**
W	92.7 (91.8, 93.6)	29.8 (28.6, 31.1)	3.0 (2.9, 3.1)	0 (0, 0)	4.6 (3.6, 5.6)
1	0 (0, 0)	47.1 (46.1, 48.8)	0 (0, 0)	0 (0, 0)	0 (0, 0)

Predicted Labels					
2	6.0 (5.9, 6.1)	20.2 (19.0, 21.4)	94.5 (93.5, 95.5)	11.5 (10.5, 12.5)	14.3 (13.4, 15.2)
3	0 (0, 0)	0 (0, 0)	2.0 (2.0, 2.0)	88.3 (87.4, 89.1)	0 (0, 0)
R	1.0 (1.0, 1.0)	2.4 (1.4, 3.4)	1.0 (1.0, 1.0)	0 (0, 0)	80.8 (79.8, 81,7)
			True Labels		

Table 3 shows the performance results in sleep apnea diagnostic agreement for endpoint 2 by SomnoMetry and the predicate device, SomnoMetry's performances showed no statistically significant differences from the predicate device's performance. The results confirm that the clinical performance achieved by SomnoMetry for diagnosing sleep apnea is substantially equivalent to the predicate device.

Table 3: Diagnosing Sleep Apnea Clinical Performance Comparison

Sleep Apnea Diagnostic Agreement Clinical Performance Comparisons	**The Subject Device SomnoMetry**						**The Predicate Device EnsoSleep**			
Bootstrapped point-estimate of median percent agreement (%) with 95% percentile bootstrap confident interval (R=1000 resamples) and likelihood ratio pairs	**All**			**REM**			**All**		**REM**	
	AHI ≥ 5	**AHI ≥ 15**	**AHI ≥ 30**	**AHI ≥ 5**	**AHI ≥ 15**	**AHI ≥ 30**	**AHI ≥ 5**	**AHI ≥ 15**	**AHI ≥ 5**	**AHI ≥ 15**
Sample Size (N)	167	167	167	167	167	167	72	72	72	72
Positive Agreement (PA)	90.6% (90.2%, 91.0%)	89.1% (88.6%, 89.6%)	83.3% (82.2%, 84.4%)	85.6% (85.1%, 86.1%)	80.0% (79.4%, 80.6%)	78.8% (77.8%, 79.8%)	91% (82%, 98%)	95% (83%, 100%)	83% (72%, 94%)	79% (56%, 94%)
Negative Agreement (NA)	92.2% (91.7%, 92.7%)	94.9% (94.6%, 95.2%)	97.5% (97.3%, 97.7%)	94.7% (94.4%, 95.0%)	94.7% (94.4%, 95.1%)	95.6% (95.4%, 95.8%)	76% (61%, 90%)	98% (94%, 100%)	89% (79%, 97%)	96% (90%, 100%)
Overall Agreement (OA)	91.2% (90.9%, 91.5%)	92.8% (92.5%, 93.1%	95.6% (95.4%, 95.8%)	88.9% (88.5%, 89.3%)	88.9% (88.7%, 89.3%)	92.4% (92.1%, 92.8%)	85% (77%, 92%)	97% (93%, 100%)	86% (79%, 93%)	92% (85%, 97%)
Likelihood Ratio (+)	11.62	17.47	33.32	16.15	15.09	17.91	3.76	52.25	7.71	22.0
Likelihood Ratio (-)	0.10	0.11	0.17	0.15	0.21	0.22	0.12	0.05	0.19	0.22

Table 3a - Younger group age under 65, N=96 subjects

	All			REM		
	AHI ≥ 5	AHI ≥ 15	AHI ≥ 30	AHI ≥ 5	AHI ≥ 15	AHI ≥ 30
Sample size	96	96	96	96	96	96
Positive Agreement (PA)	87.9% (87.3%, 88.5%)	85.7% (84.7%, 86.7%)	100% (100%, 100%)	85.6% (85.1%, 86.3%)	84.6% (83.9%, 85.3%)	81.0% (79.8%, 82.2%)
Negative Agreement (NA)	88.1% (87.3%, 88.9%)	91.7% (91.2%, 92.2%)	97.8% (97.6%, 97.9%)	93.9% (93.3%, 94.6%)	93.0% (92.5%, 93.4%)	97.3% (97.0%, 97.6%)
Overall (OA)	88.0% (87.5%, 88.5%)	89.9% (89.5%, 90.2%)	98.0% (97.8%, 98.2%)	89.1% (88.7%, 89.5%)	89.8% (89.4%, 90.2%)	94.1% (93.8%, 94.4%)
Likelihood ratio (+)	7.39	10.33	45.45	14.03	12.09	30.0
Likelihood ratio (-)	0.14	0.16	0	0.15	0.17	0.20

Table 3b - Older group age over 65, N=71 subjects.

	All			REM		
	AHI >= 5	AHI >= 15	AHI >= 30	AHI >= 5	AHI >= 15	AHI >= 30
Sample size	71	71	71	71	71	71
Positive Agreement (PA)	93.1% (92.6%, 93.6%)	91.4% (90.8%, 92.0%)	73.3% (71.7%, 74.9%)	85.2% (84.5%, 85.9%)	75.0% (73.9%, 76.1%)	74.9% (73.0%, 76.9%)
Negative Agreement (NA)	100% (100%, 100%)	100% (100%, 100%)	96.9% (96.6%, 97.2%)	94.4% (93.6%, 95.2%)	97.2% (96.8%, 97.6%)	93.3% (92.8%, 93.8%)
Overall (OA)	95.3% (95.0%, 95.6%)	96.6% (96.4%, 96.8%)	93.1% (92.8%, 93.4%)	88.4% (88.0%, 88.8%)	88.6% (88.2%, 88.9%)	90.0% (89.5%, 90.5%)
Likelihood ratio (+)	+∞	+∞	23.65	15.21	26.79	11.19
Likelihood ratio (-)	0	0	0.28	0.16	0.26	0.27

Table 3a and Table 3b show that there is no significant difference between the two subgroups. The subgroup performance matrixes demonstrated the generalizability of the SomnoMetry AI algorithm.

In the retrospective diagnostic clinical study, the final study results and statistical analysis were reported for each endpoint. The subject SomnoMetry SaMD performance showed no statistically significant differences from the predicate device performance. The results confirm that the clinical performance delivered by SomnoMetry is substantially equivalent to the predicate device across all endpoints evaluated.

The results of the software and performance testing validate that the SomnoMetry meets its requirements, performs as intended, and is as safe and effective as the predicate device. No new or different questions of safety or effectiveness have been raised.

8. Conclusion

The SomnoMetry is as safe and effective as the predicate device. The SomnoMetry has the same intended use and the indications for use fall within the scope of that for the predicate device. Many of the technological characteristics are the same for the subject and predicate devices. Any differences in technological characteristics between the subject and predicate devices have been addressed through software verification/validation testing and performance testing and do not raise any new or different questions of safety or effectiveness.

Based upon the results of the software verification and validation testing, and a clinical evaluation process consisting of valid clinical association identification, analytical validation, and clinical validation, it was determined the SomnoMetry was substantially equivalent to the predicate device.