



March 8, 2026

Onera B.V.
Pieter Ermers
Managing Director
Torenallee 42-54
Eindhoven, 5617BD
Netherlands

Re: K253668
Trade/Device Name: Onera SleepMap (SLEEPMAP)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLZ
Dated: November 21, 2025
Received: November 21, 2025

Dear Pieter Ermers:

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), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

JAY R. GUPTA -S

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

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.

K253668

?

Please provide the device trade name(s).

?

Onera SleepMap (SLEEPMAP)

Please provide your Indications for Use below.

?

SleepMap system is intended for use as an aid for physicians in the diagnosis of sleep and respiratory related disorders in adult patients (aged 18 and up), who have been prescribed a sleep study by their doctor.

SleepMap is a software- only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study recordings, including the staging of sleep, detection of arousals, leg movements, desaturations, obstructive apneas and obstructive hypopneas.

Respiratory event subtypes (central and mixed apneas; central hypopneas), RERA, Cheyne Stokes Breathing, Snoring Events, and Arrhythmia Events are not automatically detected and must be manually marked within records.

All automatically scored stages and detected events can be manually marked or edited within records during review.

All automatically scored stages, detected events and physiological signals which are retrieved, analyzed, displayed, and summarized are subject to verification by a qualified clinician

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)

?

K253668 Traditional 510(k) Summary

Prepared in accordance to 21 CFR 807.92

Contact Details:

Applicant's Name and Address: Onera B.V.
Torenallee 42-54
5617BD Eindhoven
The Netherlands

Contact Person: Pieter Ermers
VP Q&R, Managing Director
Email: Pieter.Ermers@Onerahealth.com
Phone: +31 (0)40 308 2177

Date submission was prepared: November 20, 2025

Device Name:

Trade name: Onera SleepMap
Common Name: Electroencephalograph
Classification: 21 CFR 882.1400, Automatic Event Detection
Software For Polysomnograph With
Electroencephalograph
Primary Product Code OLZ
Device Class: 2

Device Description Summary:

Onera SleepMap is a software-only medical device that analyses previously recorded physiological signals obtained during sleep through a polysomnography sleep test with the Onera STS I device. SleepMap can analyze at-home or in-lab sleep study recordings of adult patients.

Automated algorithms are applied to the raw input signals (read from a measurement file in the EDF file format originating from the Onera STS I device) in order to derive additional signals:

- a heartrate (HR) signal from the raw ECG signal. The heartrate algorithm does not include any automated arrhythmia analysis.
- a quantized position signal from the raw continuous value position signal.

Additionally, multiple algorithms are used to interpret the raw and derived signals by classifying sleep stages, sleep events and artifacts. The software automates recognition of the following sleep events: obstructive apnea and obstructive hypopnea events, arousal events, desaturation events, leg movement and PLM events.

The Onera SleepMap contains the following algorithms:

- Sleep staging algorithm, a deep learning model (AI-model) which classifies sleep stages, based on EEG, EOG and EMG inputs.
- Arousals algorithm, a Convolutional Neural Network (AI-model) which predicts arousals, based on sleep stages, EEG, EOG, EMG, ECG and nasal pressure inputs.
- Desaturation algorithm, a rule-based algorithm which detects events of minimum 3% or 4% oxygenation drop based on sleep stages and SpO2 signal inputs.
- Apnea (obstructive) detection, a rule-based algorithm which detects $\geq 90\%$ nasal pressure drops, based on sleep stages and nasal pressure signal inputs.
- Hypopneas (obstructive) detection, a rule-based algorithm which detects $\geq 30\%$ nasal pressure drops based on sleep stages, nasal pressure signal, arousal events, and desaturation event inputs.
- Leg Movement algorithm, a rule-based algorithm which detects (repetitive) EMG amplitude increasements, based on sleep stages, EMG signal and respiratory event inputs.
- Artifact algorithms, rule-based algorithms which detect artifacts, based on SpO2, EEG, EOG, EMG and heart rate inputs.

Additionally, clinical users can manually annotate: respiratory event subtypes (central and mixed apneas and central hypopneas), RERA, Cheyne Stokes Breathing, Snoring Events, and Arrhythmia Events.

Automated Annotations	Manual Annotations
Sleep Stages (N1, N2, N3, REM, WAKE)	Sleep Stages (N1, N2, N3, REM, WAKE, unstaged*)
Apnea (Obstructive)	Apnea (Obstructive, Central*, Mixed*)
Hypopnea (Obstructive)	Hypopnea (Obstructive, Central*)
Desaturation	Desaturation
Arousal	Arousal
Leg Movement	Leg Movement

Periodic Leg Movement	Periodic Leg Movement
	RERA*
	Cheyne-Stokes Breathing*
	Snoring*
	Arrhythmia*
Signal artifacts on EEG, EOG, EMG, ECG, SpO2, HR signals	Signal artifacts on EEG, EOG, EMG, ECG, SpO2, HR, Respiratory Effort*, Respiratory Flow*, Position*, Activity*, Sound* and Nasal Pressure signals*

* Events are not automatically detected but can be additionally manually annotated.

The raw signals, derived signals and all automated analysis results (annotations) must be visually inspected and reviewed by sleep analysts and physicians prior to the results being integrated into a sleep study report.

SleepMap calculates aggregated metrics and indexes on the set of annotations resulting from the sleep analyst or physician review and integrates these into a technical sleep report that can be previewed.

The technical sleep study report summarizes the sleep stage annotations in a hypnogram, provides the aggregated metrics and indexes, and the technician notes into a PDF document which is the main output of SleepMap. The technical sleep study report is transferred to the Onera Digital Health Platform for storage and is used by the physician to diagnose the sleep disorder.

Intended Use/Indications for Use:

SleepMap is intended for use as an aid for physicians in the diagnosis of sleep and respiratory related disorders in adult patients (aged 18 and up), who have been prescribed a sleep study by their doctor.

SleepMap is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study recordings, including the staging of sleep, detection of arousals, leg movements, desaturations, obstructive apneas and obstructive hypopneas.

Respiratory event subtypes (central and mixed apneas; central hypopneas), RERA, Cheyne Stokes Breathing, Snoring Events, and Arrhythmia Events are not automatically detected and must be manually marked within records.

All automatically detected stages and detected events can be manually marked or edited within records during review.

All automatically scored stages, detected events and physiological signals which are retrieved, analyzed, displayed, and summarized are subject to verification by a qualified clinician.

The Onera SleepMap has similar indications as the predicate device.

Legally marketed Predicate Devices:

510(k) Number	Device Name	Type
K162627	EnsoSleep	Predicate device
K162140	RemLogic	Reference device

Technological Comparison:

The table below provides a comparison between the Onera SleepMap and the predicate device.

Characteristic	Proposed device Onera SleepMap	Predicate device EnsoSleep	Discussion
General			
Manufacturer	Onera B.V., The Netherlands	EnsoData Inc., USA	--
510(k) number	K253668	K162627	--
Regulation number	21 CFR 882.1400	21 CFR 882.1400	Identical
Product code	OLZ	OLZ	Identical
Indications general	SleepMap is intended for use as an aid for physicians in the diagnosis of sleep and respiratory related disorders in adult patients, (aged 18 and up), who have been prescribed a sleep study by their doctor.	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.	Similar
	SleepMap is a software-only medical device to be used under the supervision of a clinician to analyze physiological signals and automatically score sleep study recordings, including the staging of sleep, detection of arousals, leg movements, desaturations, obstructive apneas and obstructive hypopneas.	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.	Similar
	Respiratory event subtypes (central and mixed apneas; central hypopneas), RERA, Cheyne Stokes Breathing, Snoring Events, and Arrhythmia Events are not automatically detected and must be manually marked within records.	Central apneas, mixed apneas, and hypopneas must be manually marked within records.	Similar.

Characteristic	Proposed device Onera SleepMap	Predicate device EnsoSleep	Discussion
	All automatically scored stages and detected events can be manually marked or edited within records during review. All automatically scored stages, detected events and physiological signals which are retrieved, analyzed, displayed, and summarized are subject to verification by a qualified clinician.	All automatically scored events are subject to verification by a qualified clinician	Similar
Indications – Environment	Physician office (data analysis and reporting). No limitation on where data are acquired.	Physician office (data analysis and reporting). No limitation on where data are acquired.	Identical
Patient population	Adults only	Adults only	Identical
Operating principle	1. Automated analysis of sleep study data 2. Review by a qualified clinician 3. Making the data available for display in a report	1. Automated analysis of sleep study data 2. Review by a qualified clinician 3. Making the data available for display in a report	Identical
System setup	• Processing, scoring and analysis of signal data: cloud servers • Reviewing, report generation: cloud server & browser based	• Processing, scoring and analysis of signal data: cloud servers • Reviewing, report generation: stand-alone PC application	Similar
Generic performance data			
Input signals	• EEG • EOG • EMG • SpO2 • ECG • Respiratory Effort • Respiratory Flow • Position • Activity • Sound SPL • Nasal pressure • EMG leg	• EEG • EOG • EMG • SpO2 • ECG • Respiratory Effort • Respiratory Flow • Position • Activity • Sound SPL • Nasal pressure • EMG leg • Pulse Rate	Similar The subject device derives the heart rate from the ECG, whilst the predicate device uses pulse rate as an input. The difference is not deemed to be clinically relevant.

Characteristic	Proposed device Onera SleepMap	Predicate device EnsoSleep	Discussion
Derived signals	Heart rate (ECG derived)	NA -	Different The subject device derives the heart rate from the ECG, whilst the predicate device uses pulse rate as an input. This difference does not lead to different questions of safety and effectiveness as the technology is similar to the technology used in the reference device Embla Systems (Natus), RemLogic (K162140) and V&V results showed the used algorithm is sufficiently accurate, see DHF8001094 HR Algorithm validation report
	Quantized Position	Quantized Position	Different The subject device derives the Quantized position from the continuous position signal, whilst the predicate device uses quantized position as an input. This difference does not lead to different questions of safety and effectiveness as the technology is similar to the technology used in the reference device Embla Systems (Natus), RemLogic (K162140) and V&V results showed the used algorithm is sufficiently accurate, see DHF8001152_Body position validation report
Sleep stages (annotations; automatically scored)	- Wake - N1 - N2 - N3 - REM	- Wake - N1 - N2 - N3 - REM	Identical See DHF8001073 Automated scoring performance validation report.

Characteristic	Proposed device Onera SleepMap	Predicate device EnsoSleep	Discussion
Sleep events (annotations; automatically detected)	• Arousal events • Desaturation events • Respiratory events (apnea obstructive and hypopnea obstructive) • Leg movement events, Periodic Leg Movement • Artifact events (HR, SpO2, EEG, EOG, EMG, ECG)	• Arousal events • Respiratory events (apnea and hypopnea) • Leg movement events	Similar The subject device identifies and scores artifacts based on the input signal quality indicators (error values) The difference is not deemed to be clinically relevant.
Sleep events (annotations; manually scored)	• Respiratory event subtypes (apnea central, apnea mixed, hypopneas central) • RERA • Cheyne Stokes Breathing • Snoring Events • Arrhythmia Events • Artifacts events (Respiratory Effort, Respiratory Flow, Position, Activity, Sound, Nasal Pressure signals)	Yes, requires 3 rd party sleep study viewer	Different The subject device allows that annotations be manually scored within the signal viewer. This difference does not raise different questions of safety and effectiveness.
Manual annotation editing (stages, events)	• Wake • N1 • N2 • N3 • REM • Arousal events • Desaturation Events • Respiratory events (apnea obstructive and hypopnea obstructive) • Leg movement events • Artifact events (HR, SpO2, EEG, EOG, EMG, ECG) • Unstaged • Respiratory subevents (apnea central, apnea mixed, hypopnea central) • RERA • Cheyne Stokes Breathing • Snoring Events • Arrhythmia Events • Artifact events (Respiratory effort, Respiratory flow, Position, Activity, Sound, Nasal pressure signals)	Yes, requires 3 rd party sleep study viewer	Different The subject device allows that annotations be manually edited within the signal viewer. This difference does not raise different questions of safety and effectiveness.

Characteristic	Proposed device Onera SleepMap	Predicate device EnsoSleep	Discussion
Sleep study statistics	• Total recording time • Lights Off/On • Total sleep time • Total/% time in sleep stages • Sleep Latency • Wake After Sleep Onset • Sleep Efficiency • REM latency	• Total recording time • Lights Off/On • Total sleep time • Total/% time in sleep stages • Sleep Latency • Wake After Sleep Onset • Sleep Efficiency • REM latency	Identical
Sleep study metrics	• Respiratory • SpO2 • Arousal • Snoring • Position • Cardiac • Arrhythmia • Movements	• Respiratory • SpO2 • Arousal • Snoring • Position • Cardiac • Arrhythmia • Movements	Identical
Technical characteristics			
Automated study upload and download	Yes	Yes	Identical
Automatically initiates study scoring	Yes	Yes	Identical
Allows editing in sleep study viewers	Yes, within SleepMap	Yes, requires 3 rd party sleep study viewer	Different The subject device allows annotations to be edited within the signal viewer. This difference does not raise different questions of safety and effectiveness.
Sleep study reporting	Yes	Yes	Identical
Compatible input devices	Onera STS I	Various PSG systems	Different The subject device is intended for analyzing measurement data from a single input device, whilst the predicate device supports multiple PSG systems. This difference does not raise different questions of safety and effectiveness.
Input data format	EDF	EDF	Identical
Report data format	PDF	PDF	Identical

Characteristic	Proposed device Onera SleepMap	Predicate device EnsoSleep	Discussion
Compatibility	Browser-based (Microsoft Edge or Google Chrome)	Operates on any PC with Windows 7 and 8 operating system platforms.	Similar. The difference in compatibility depends on the system setup. Therefore, this difference does not raise new questions on safety or effectiveness.
Cybersecurity	Authentication controls, authorization controls, cryptographic controls, access controls, integrity controls, intrusion & availability monitoring controls, and database controls.	Authentication controls, authorization controls, cryptographic controls, access controls, checksum controls, software distribution controls, intrusion detection system controls, network and systems controls, and database controls.	Similar. The differences in cybersecurity controls depends on the system setup. Therefore, this difference does not raise new questions on safety or effectiveness.
Cloud Service provider	AWS	AWS	Identical
Network requirements	High-speed internet connection, above 200 kb/s recommended.	High-speed internet connection, above 200 kb/s recommended.	Identical

The Onera SleepMap has similar indications as the predicate device, where some elements of the indications have been rephrased to be more specific.

The Onera SleepMap has the same technological characteristics as the predicate device except for the following features:

- The Onera SleepMap is a native cloud-based application (browser) where the predicate device is a server connected PC application (executable)
- The Onera SleepMap derives the heart rate from the ECG input signal, where the predicate device utilizes both ECG and pulse rate as input signals.
- The Onera SleepMap allows for the manual review and editing of annotations within the application, where the predicate device requires a third-party sleep study viewer.
- The Onera SleepMap applies automated algorithms on PSG measurements acquired with Onera STS I devices only, where the predicate device is measurement device agnostic.

These differences do not raise new questions on the safety or effectiveness of the Onera SleepMap.

Summary of non-clinical testing:

Compliance with the following standards, applicable to the system, was verified:

- EN IEC 62304:2006/A1:2015
- EN 82304-1:2017
- EN ISO 20417:2021
- EN ISO 15223-1:2021

Documentation was prepared as recommended in FDA's Guidance for Industry and FDA Staff, 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'.

For the Onera SleepMap system, a usability engineering process was followed to ensure usability risks were sufficiently mitigated. The Usability engineering activities and report concludes that the system was found to be safe and effective to use:

- Onera SleepMap can be used by representative users under simulated use conditions without producing patterns of failures that could result in harm to users and has been found to be reasonably safe and effective for those intended users, uses, and use environments.
- The instructions provided in the Instructions for Use, Clinician guide and the CloudOps playbook are effective, as demonstrated by overall usability findings and qualitative feedback.

Summary of clinical testing:

The Automated Scoring Service AI models and algorithms (sleep staging, arousal event detection, desaturation event detection, obstructive apnea event detection, obstructive hypopnea event detection, leg movement and PLM event detection) have been validated using a validation data set consisting of 98 PSG night studies recorded with the Onera STS I device on 98 unique patients. The recordings consist of N=72 studies performed in the home environment in the United States, acquired from August 2023 to August 2025, and N=26 studies performed in the clinic environment in Germany, acquired from September 2022 to April 2024.

All the recordings have been manually analyzed/scored by 3 independent, US based certified sleep professionals in compliance with AASM scoring guidelines.

A 2 out of 3 (2/3) majority scoring is constructed as ground truth reference to evaluate the Automated Scoring Service algorithms performance.

For all evaluated metrics, the performance point-estimate is calculated from the cross-sectional data. Confidence Interval (CI) is calculated as two-sided 95% bootstrap percentile method (R=1000 resamples) of using subjects as the resampling unit.

The following formulas have been used in the tables below:

Agreement metrics definition, where TP = true positive, FN = false negative, FP = false positive, TN = true negative.

Positive agreement (PA) = $100\% * TP / (TP + FN)$

Negative agreement (NA) = $100\% * TN / (FP + TN)$

Overall agreement (OA) = $100\% * (TP + TN) / (TP + FP + TN + FN)$

False Discovery Rate (FDR) = $100\% * FP / (FP + TP)$

Sleep Staging Performance

	Overall-Epochs SleepMap vs 2/3 Majority Sleep Staging Performance					
	(N=98 subjects, 98937 epochs)		Point-estimate of Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=1000 resamples of subjects)			
	Positive Epochs	Negative Epochs	Positive Agreement (PA)	Negative Agreement (NA)	Overall Agreement (OA)	False Discovery Rate (FDR)
Wake	19738 (19.3%)	79199 (77.5%)	82.5% (78.9%, 85.5%)	98.4% (97.6%, 99.1%)	95.3% (94.1%, 96.2%)	7.1% (4.3%, 10.2%)
N1	1316 (1.3%)	97621 (95.5%)	69.6% (65.0%, 74.5%)	91.2% (89.9%, 92.4%)	90.9% (89.5%, 92.1%)	90.4% (89.1%, 91.6%)
N2	51752 (50.6%)	47185 (46.2%)	75.4% (72.3%, 78.4%)	92.1% (91.0%, 93.2%)	83.4% (81.5%, 85.2%)	8.7% (7.4%, 10.1%)
N3	9025 (8.8%)	89912 (88.0%)	85.6% (82.9%, 88.4%)	93.9% (92.1%, 95.4%)	93.2% (91.6%, 94.4%)	41.4% (34.1%, 48.4%)
REM	17106 (16.7%)	81831 (80.1%)	82.7% (79.8%, 85.4%)	97.8% (97.1%, 98.3%)	95.2% (94.5%, 95.8%)	11.5% (8.8%, 14.7%)
Total	98937 (96.8%)	-	78.9% (76.8%, 81.0%)	94.7% (94.2%, 95.2%)	91.6% (90.7%, 92.4%)	21.1% (19.0%, 23.2%)
Disagreement epochs*	3282 (3.2%)	-	-	-	-	-

'Disagreement epochs' represents epochs (n=3282) which are excluded from the sleep staging performance validation, as for these epochs the scorers did not reach a 2/3 majority agreement and thus a ground-truth could not be obtained. The scoring was performed by three independent US certified sleep professionals.

Sleep Event Performance

	Overall-Epochs SleepMap vs 2/3 Majority Sleep Detection of Sleep Events Performance					
	(N=98 subjects, 102219 epochs)		Point-estimate of Percent Agreement (%) with 95% percentile bootstrap confidence interval (R=1000 resamples of subjects)			
	Positive Epochs	Negative Epochs	Positive Agreement (PA)	Negative Agreement (NA)	Overall Agreement (OA)	False Discovery Rate (FDR)
Sleep Disordered Breathing	15836 (15.5%)	86383 (84.5%)	78.2% (72.8%, 82.7%)	90.7% (89.7%, 91.7%)	88.8% (87.7%, 89.8%)	39.3% (32.8%, 46.6%)
Apnea	6582 (6.4%)	95637 (93.6%)	85.7% (79.0%, 89.9%)	97.0% (96.4%, 97.6%)	96.3% (95.6%, 96.9%)	33.6% (25.6%, 46.1%)
Obstructive Apnea	4753 (4.6%)	97466 (95.4%)	84.5% (75.3%, 89.7%)	95.4% (94.1%, 96.6%)	94.9% (93.6%, 96.0%)	52.7% (41.2%, 67.1%)
Hypopnea	8945 (8.8%)	93274 (91.2%)	56.9% (52.2%, 60.9%)	91.9% (90.9%, 92.9%)	88.8% (87.7%, 90.1%)	59.8% (55.6%, 64.3%)
Obstructive Hypopnea	8932 (8.7%)	93287 (91.3%)	56.9% (52.2%, 60.9%)	91.9% (90.9%, 92.9%)	88.8% (87.7%, 90.1%)	59.8% (55.7%, 64.4%)
Desaturation	15737 (15.4%)	86482 (84.6%)	87.5% (85.0%, 89.4%)	85.6% (83.6%, 87.5%)	85.9% (84.1%, 87.5%)	47.5% (40.5%, 55.0%)
Arousal	15119 (14.8%)	87100 (85.2%)	59.8% (54.4%, 64.7%)	95.1% (94.3%, 95.8%)	89.9% (89.0%, 90.7%)	32.1% (28.6%, 36.3%)
Leg Movement	4718 (4.6%)	97501 (95.4%)	77.6% (74.2%, 80.6%)	86.9% (84.2%, 89.3%)	86.5% (83.9%, 88.7%)	77.8% (72.5%, 82.4%)
Periodic Leg Movement	1977 (1.9%)	100242 (98.1%)	72.0% (62.2%, 78.5%)	91.4% (88.9%, 93.6%)	91.0% (88.6%, 93.2%)	85.8% (79.6%, 91.7%)

The heartrate (HR) algorithm was validated using a validation data set consisting of 5 min time intervals from N=249 PSG night studies recorded with the Onera STS I on 215 unique patients. The recordings consist of N=171 studies performed in the home environment in the United States, acquired from August 2023 to August 2025, and N=78 studies performed in the clinic environment in Germany between September 2022 and April 2024.

All the recordings have been manually annotated by 2 independent cardiac technologists. The disagreements in annotations between the 2 annotators were adjudicated by an expert board certified cardiologist from Florida, USA. The final manual annotations constitute the ground truth for validation of the algorithm.

The HR output showed an absolute error of less than 3 bpm for over 99% of runs, with only brief transient deviations less than 4s.

Based on the information included in this submission, it was concluded that the Onera SleepMap system is as safe, as effective and performs as well as the legally marketed device identified above.