July 3, 2025

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

Re: K243220
Trade/Device Name: Onera STS 2 (ONERA STS 2)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, OLV
Dated: June 3, 2025
Received: June 3, 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243220

Device Name
Onera STS 2

Indications for Use *(Describe)*
Onera STS 2 measures and records multiple physiological parameters from a patient during a sleep study, which are used by clinicians to decide on the diagnosis of sleep disorders.

Onera STS 2 is intended to be used on a patient who has been prescribed a polysomnography study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but applied by a layperson.

The recorded data will be made available to the healthcare professional to assist in the diagnosis of sleep disorders.

The device is intended to be used for adults.

The device is not a life supporting physiological monitor.

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.

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K243220 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) 403 082 177

Date prepared: July 2, 2025

Device Name:

Trade name:	Onera Sleep Test System 2 / Onera STS 2
Common Name:	Ventilatory Effort Recorder
Classification:	21 CFR 868.2375, Breathing frequency monitor
Primary Product Code	MNR
Secondary Product Code	OLV
Device Class:	2

Device Description:

Onera Sleep Test System 2 (Onera STS 2) is a hardware, wearable system for measuring physiological signals during a sleep study. The device can be used in the home (Home Healthcare Environment) as well as in Professional Healthcare Facilities.

The device measures EEG, EOG, EMG, ECG, respiratory signals, cannula based respiratory flow, oxygen saturation, activity, position, ambient light level and sound pressure level.

The ECG signal is not intended for diagnosis of cardiac disorders, except for the manual determination of arrhythmia during polysomnography studies.

The Onera STS 2 does not provide any automated output like heart rate, assessments of arrhythmia, heart rate variability, or other related heart rate measurement functions.

Onera STS 2 consists of five Sensors applied on the forehead, upper chest area, abdomen and lower leg area (both left and right leg).

The Sensors should be placed on intact skin. During the night measurement it is not needed to inspect the application sites. The Sensors encrypt the recorded signals and upload the measurement data during the night to the Patient App installed on the patient's phone via Bluetooth. The Patient App securely transfers the data to the cloud interface for further processing once all data has been uploaded. The output of the system is represented by a file in EDF format which contains the recorded (physiological) signals. EDF files can be read by any application software that accepts such files as input.

It is not possible to relocate the Sensors during a sleep study since the Sensor is single-use and for one sleep study only.

Intended Use:

Onera STS 2 measures and records multiple physiological parameters from a patient during a sleep study, which are used by clinicians to decide on the diagnosis of sleep disorders.

Onera STS 2 is intended to be used on a patient who has been prescribed a polysomnography study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but applied by a layperson.

The recorded data will be made available to the healthcare professional to assist in the diagnosis of sleep disorders.

The device is intended to be used for adults.

The device is not a life supporting physiological monitor.

The Onera Analysis Service has the same indications as the predicate device.

Legally marketed Predicate Device:

510(k) Number	Device Name	Type
K223573	Onera STS	Predicate device

Technological Comparison:

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

Characteristic	Proposed device Onera STS 2	Predicate device Onera STS 1	Discussion
General			
Manufacturer	Onera B.V., The Netherlands	Onera B.V., The Netherlands	--
510(k) number	K243220	K223573	--
Regulation number	21 CFR 868.2375	21 CFR 868.2375	Same
Product code	MNR	MNR	Same

Characteristic	**Proposed device Onera STS 2**	**Predicate device Onera STS 1**	**Discussion**
Indications for Use Statement	Onera STS 2 measures and records multiple physiological parameters from a patient during a sleep study which are used by clinicians to decide on the diagnosis of sleep disorders. Onera STS 2 is intended to be used on a patient who has been prescribed a polysomnography study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but applied by a layperson. The recorded data will be made available to the healthcare professional to assist in the diagnosis of sleep disorders. The device is intended to be used for adults.	Onera STS measures and records multiple physiological parameters from a patient during a sleep study which are used by clinicians to make a decision on the diagnosis of sleep disorders. Onera STS is intended to be used on a patient, who has been prescribed a sleep study by a healthcare professional. The device is designed to be used under the direction of a physician or trained technician but applied by a layperson. The recorded data will be made available to a healthcare professional to assist in the diagnosis of sleep disorders. The device is intended to be used for adults.	Identical
Intended Use Environment	Home and professional environments.	Home and professional environments.	Identical
Limitations of Use	The device is not a life supporting physiological monitor. The ECG signal is not intended for diagnosis of cardiac disorders, except for the manual determination of arrhythmia during polysomnography studies. The Onera STS 2 does not provide any automated output like heart rate, assessments of arrhythmia, heart rate variability, or other related heart rate measurement functions.	The device is not a life supporting physiological monitor.	Identical

Characteristic	**Proposed device Onera STS 2**	**Predicate device Onera STS 1**	**Discussion**
Operating principle	1. Measuring of electrophysiological and other (sound, flow, position) signals via a range of sensors. 2. Recording of the data. 3. Extracting the data offline via dedicated software 4. Making the data available for display on a suitable platform	1. Measuring of electrophysiological and other (sound, flow, position) signals via a range of sensors. 2. Recording of the data. 3. Sending data to a cloud platform via a connected smartphone. 4. Making the data available for display on a suitable platform	Similar. The wireless connection instead of wired connection for data extraction does not lead to new questions on safety or effectiveness as supported by the risk analysis.
Energy	Measuring of electrophysiological signals and other signals (sound, flow, …). Non-rechargeable battery powered devices.	Measuring of electrophysiological signals and other signals (sound, flow, …). Rechargeable battery powered devices.	Comparable. The different battery type does not raise new questions on safety or effectiveness as supported by the risk analysis and electrical safety testing.
Sterility	No sterile parts involved	No sterile parts involved	Identical
Materials / Biocompatibility	Materials biocompatible conform ISO10933 series including the adhesive patches	Materials biocompatible conform ISO10933 series including the adhesive patches	Identical

System setup	• 4 wearable disposable sensors:
	  ○ Head
	  ○ Chest
	  ○ Flow
	  ○ Leg
	• Smartphone app to transfer data to cloud platform
	• Cloud platform to make data available to users.
		• 4 wearable reusable sensors:
		  ○ Head
		  ○ Chest
		  ○ Flow
		  ○ Leg
		• Software to extract data and make available to users.
			Comparable. The sensors being disposable reduces risks related to reuse (e.g. cleaning).
			The app and cloud platform are different technologies to consolidate the sensor data in an output file and make it available to users. This different technology does not raise different questions on safety or effectiveness.

Generic performance data			
Recording time	16 hours	16 hours	Both are sufficient for the intended use.

Characteristic	Proposed device Onera STS 2	Predicate device Onera STS 1	Discussion
Data interface	Bluetooth	USB	Similar. The Bluetooth interfaces link the sensors to a connected smartphone. The wireless connection instead of wired connection for data extraction does not raise different questions of safety or effectiveness as supported by the risk analysis.
Data output file	EDF	EDF	Identical
Expected service life (reusables)	N/A, single use device	200 cycles or 5 years	The sensors being disposable reduces risks related to reuse (e.g. cleaning).
Sensors IP class	IP54	IP54	Identical
Measured parameters (# channels, location, sample rate, resolution, accuracy)			
EEG	• 2 channels • Frontal R, frontal L • Sampling: 256Hz • 16bit	• 2 channels • Frontal R, frontal L • Sampling: 256Hz • 16bit	Identical
EOG	• 2 channels • EOG R, EOG L • Sampling: 256Hz • 16bit	• 2 channels • EOG1, EOG2 • Sampling: 256Hz • 16bit	Identical
EMG head	• 2 channels • EMG mas R, EMG mas L • Sampling: 256Hz • 16bit	• 2 channels • EMG mas R, EMG mas L • Sampling: 256Hz • 16bit	Identical
EMG leg (one leg)	• 1 channel • leg - specific location • Sampling: 256Hz • 16bit	• 1 channel • leg - specific location • Sampling: 256Hz • 16bit	Identical
SpO2 forehead	• SpO2, PPG red & infrared • forehead • Sampling: 2Hz • 1% resolution • 3% at 70-100%SpO2; Pulse rate 30-200bpm	• SpO2, PPG red & infrared • forehead • Sampling: 2Hz • 1% resolution • 4% at 70-100%SpO2; Pulse rate 30-200bpm	Comparable. The improved accuracy does not raise different questions of safety or effectiveness.
ECG	• 1 channel • Chest • Sampling: 256Hz • 16bit • Noise < 1 µVRMS, CMRR: >=80dB	• 1 channel • Chest • Sampling: 256Hz • 16bit • Noise < 1 µVRMS, CMRR: >=80dB	Identical
Respiratory effort	• 1 channel • Chest (derived via measured bioimpedance) • Sampling: 64Hz • 16bit	• 1 channel • Chest (derived via measured bioimpedance) • Sampling: 64Hz • 16bit	Identical

Characteristic	Proposed device Onera STS 2	Predicate device Onera STS 1	Discussion
Respiratory flow	• 1 channel • Nasal cannula • Sampling 256Hz • 16bit	• 1 channel • Nasal cannula • Sampling 256Hz • 16bit	Identical
Position	• 1 channel • Chest sensor (derived from 3D accelerometer) • Sampling 1Hz • 1°	• 1 channel • Chest sensor (derived from 3D accelerometer) • Sampling 1Hz • 1°	Identical
Activity chest	• 1 channel • Chest sensor (derived from 3D accelerometer) • Sampling 16Hz • 15bits • 0 to 6g	• 1 channel • Chest sensor (derived from 3D accelerometer) • Sampling 16Hz • 15bits • 0 to 6g	Identical
Sound pressure	• 1 channel • Chest – microphone • Sampling 64Hz (3kHz microphone) • 0.1 dB resolution	• 1 channel • Chest – microphone • Sampling 64Hz (3kHz microphone) • 0.1 dB resolution	Identical
Environmental conditions			
Operating temperature	5°C - 40°C	10°C - 40°C	Comparable; the subject device is usable at lower temperatures
Operating relative humidity	10% - 90%	10% - 90%	Identical
Storage temperature	12°C - 28°C	10°C - 40°C	The more limited storage condition is clearly indicated on the labeling and does not raise different questions of safety or effectiveness.
Transport temperature	-7°C - 50°C	10°C - 40°C	The more extended transport conditions do not raise different questions of safety or effectiveness.
Conformance to Standards			
EMC	IEC 60601-1-2	IEC 60601-1-2	Identical
Basic Safety and essential performance	IEC 60601-1	IEC 60601-1	Identical
Safety and essential performance of electrocardiographs	IEC 60601-2-25	IEC 60601-2-25	Identical
Safety and essential performance of Electroencephalographs	IEC 80601-2-26	IEC 80601-2-26	Identical

Characteristic	Proposed device Onera STS 2	Predicate device Onera STS 1	Discussion
Safety and essential performance of Electromyographs and evoked response equipment	IEC 60601-2-40	IEC 60601-2-40	Identical
Safety and essential performance of pulse oximeter equipment	IEC 80601-2-61	IEC 80601-2-61	Identical

The Onera Sleep Test System 2 has the same technological characteristics as the predicate device except for the following features:

- The Onera STS 2 has a wireless connection via the cloud for data retrieval, in comparison to the wired/networked connectivity of the predicate device.
- The Onera STS 2 system is a single use system in comparison to the re-usable predicate device.

These differences do not raise different questions of the safety or effectiveness of the Onera Sleep Test System 2 and valid scientific evidence has been submitted to account for the changes to the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions:

Performance testing on the Onera STS 2 device confirmed that the device conforms to the defined requirements including the applicable requirements of the following standards:

- IEC 60601-1 Basic safety and essential performance
- IEC 60601-1-2 EMC
- IEC 60601-2-25 Basic safety and essential performance of electrocardiographs
- IEC 80601-2-26 Basic safety and essential performance of electroencephalographs
- IEC 60601-2-40 Basic safety and essential performance of electromyographs and evoked response equipment
- ISO 80601-2-61 Basic safety and essential performance of pulse oximeter equipment
- ANSI/AAMI EC 12 Disposable Electrodes

Biocompatibility testing was performed as listed in the table below:

Test	Results	Conclusions
Cytotoxicity	Exposure of L929 mammalian cell cultures to test item extracts shows no cytotoxic potential.	No cytotoxic potential
Irritation or Intracutaneous reactivity	Electrode and enclosure did not produce any primary dermal reaction after exposure to the skin of New Zealand White Rabbits.	Nonirritating potential
Sensitization	Electrode and enclosure did not induce any skin reaction scores at the challenge exposure following an induction phase when applied topical to albino guinea pigs.	No sensitization potential

A risk management process conforming with ISO 14971 was completed for the device. A usability engineering process conforming with IEC 62366-1 was completed for the device. All device software was developed in a process conforming with IEC 62304.

Summary of Clinical testing

Spo2 measurement accuracy:

SpO_2 accuracy testing was conducted, as recommended by the FDA Guidance for Industry and FDA Staff Pulse Oximeters – Premarket Notification Submissions [510(k)s], during induced hypoxia studies on 12 healthy, light-to-dark-skinned male (9) and female (3) subjects aged between 23 and 46 years old, in a reclined position, in an independent research laboratory. The measured arterial hemoglobin saturation values (SpO_2) of the sensor were compared to the arterial hemoglobin oxygen (SaO_2) values, determined from blood samples with a laboratory co-oximeter.

The accuracy of the sensor was calculated using the root-mean-squared difference (A_{rms} value) between the measured values and the reference values for all subjects over the SpO_2 range of 70 - 100 %. The SpO_2 accuracy testing, and the data analysis were performed as per ISO 80601-2-61.

The Onera STS2 SpO2 showed an accuracy of ±2.5% in the range 70-100%, which is within the pass/fail criteria described in ISO80601-2-61:2019 Clause 201.12.1.101.1.

Based on the information included in this submission, it was concluded that the Onera Sleep Test System 2 is as safe, as effective and performs as well as the legally marketed device identified above.