August 18, 2023

Onera B.V.
Ruben de Francisco Martin
Managing Director
Torenallee 42-54
Eindhoven, NB 5617BD
Netherlands

Re: K223573
Trade/Device Name: Onera Sleep Test System (Onera STS)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, OLV
Dated: July 20, 2023
Received: July 21, 2023

Dear Ruben de Francisco Martin:

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,

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

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.

510(k) Number *(if known)*
K223573

Device Name
Onera Sleep Test System (STS)

Indications for Use *(Describe)*
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.

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

Acc. to 807.92

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

Contact Person: Ruben de Francisco Martin
Managing Director
Email: ruben@onerahealth.com
Phone: +31 (0) 403 082 177

Date submission was prepared: October 30, 2022

Device Name:

Trade name:	Onera Sleep Test System (STS)
Common Name:	Ventilatory Effort Recorder
Classification:	21 CFR 868.2375, Breathing frequency monitor
Product Codes:	MNR, OLV
Device Class:	2

Product Description:
Onera STS is a wearable system for measuring (physiological) signals during a sleep study. The device can be used in home (Home Healthcare Environment) as well as Professional Healthcare Facilities, to perform the sleep study.

Onera STS consists of four sensors applied on the forehead, upper chest area, abdominal and lower leg area.

The sensors measure EEG, EOG, EMG, ECG, bioimpedance based respiratory effort, bioimpedance based respiratory flow, cannula based respiratory flow, oxygen saturation, activity, position, and sound pressure level.

The study preparation and data retrieval are done in a professional/clinical environment by the trained operator. The device is provided to the user by the trained operator.

The device is not a life supporting physiological monitor.

Indications for Use:
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.

Legally marketed devices to which substantial equivalence is claimed

510(k) Number	Device Name	Type
K210593	Onera STS	Predicate device

Device modifications

The table below provides an overview of the proposed change to the Onera STS device in comparison with the predicate and currently marketed Onera STS device.

#	Scope	Description
1	Labeling	Extend the use time from 8 hours to 16 hours. The extension is supported by new skin irritation testing and 16-hour wear time testing as part of design verification and validation activities

Substantial Equivalence

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

Characteristic	Proposed device Onera STS	Currently cleared Onera STS	Result
Manufacturer	Onera B.V., The Netherlands		--
510(k) number	K223573	K210593	--
Regulation number	21 CFR 868.2375	21 CFR 868.2375	Identical
Product code	MNR	MNR	Identical
Indications general	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 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 a healthcare professional to assist in the diagnosis of sleep disorders.	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 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 a healthcare professional to assist in the diagnosis of sleep disorders.	Identical

Characteristic	Proposed device Onera STS	Currently cleared Onera STS	Result
Indications – Patient population	The device is intended to be used for adults.	The device is intended to be used for adults.	Identical
Indications – Environment	Home and professional environments.	Home and professional environments.	Identical
Indications - Limitations	The device is not intended to monitor or diagnose the patient and does not issue alarms	The device is not intended to monitor or diagnose the patient and does not issue alarms	Identical
Operating principle	Measuring of electrophysiological and other (sound, flow, position) signals via a range of sensors. Recording of the data. Making the data available for display on a suitable platform	Measuring of electrophysiological and other (sound, flow, position) signals via a range of sensors. Recording of the data. Making the data available for display on a suitable platform	Identical
Energy	Measuring of electrophysiological signals and other signals (sound, flow, …). Battery powered devices.	Measuring of electrophysiological signals and other signals (sound, flow, …). Battery powered devices.	Identical
Materials	Patches are included with the device and found biocompatible (see summary below)	Patches are included with the device and found biocompatible (see summary below)	Identical
Recording time	8 hours	16 hours	Extended use time
Measured parameters	EEG (2 channels)	EEG (2 channels)	Identical
	EOG (2 channels)	EOG (2 channels)	Identical
	EMG head (2 channels)	EMG head (2 channels)	Identical
	EMG leg (one leg)	EMG leg (one leg)	Identical
	SpO2 forehead	SpO2 forehead	Identical
	ECG (1 channel)	ECG (1 channel)	Similar
	Respiratory effort (one channel via bioimpedance)	Respiratory effort (one channel via bioimpedance)	Identical
	Respiratory flow via nasal cannula	Respiratory flow via nasal cannula	Identical
	Sound pressure	Sound pressure	Identical
Derived parameters	Position (1 channel derived from 3D accelerometer)	Position (1 channel derived from 3D accelerometer)	Identical
	Activity (chest)	Activity (chest)	Identical
Operating temperature	10°C - 40°C	10°C - 40°C	Identical
Operating relative humidity	10% - 90%	10% - 90%	Identical

The technology to obtain information on respiratory effort is equivalent to that of the defined reference device.

Other than the extended use time described above, there are no differences in technological characteristics between this Onera STS device and the Onera STS device cleared under K210593. The intended use of the device is the same as the predicate device.
None of the indicated changes introduce new questions of safety or effectiveness.

Summary of Performance Testing
Performance testing on the changed Onera STS device confirmed that the changed device conforms to the defined requirements.

The proposed Onera STS is found in compliance with 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
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

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
No clinical data was required to support equivalence.

Conclusion
Based on the information included in this submission, it was concluded that the proposed changed Onera STS device is substantially equivalent to the predicate device.