April 6, 2022

Onera B.V.
Ruben De Francisco Martin
Managing Director
Torenallee 42-54
Eindhoven, North Brabant 5617BD
Netherlands

Re: K210593
Trade/Device Name: Onera Sleep Test System (STS)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, OLV
Dated: March 4, 2022
Received: March 7, 2022

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 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)*
K210593

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Acc. to 807.92

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

Contact Person: Ruben de Francisco Martin
Managing Director
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Date submission was prepared: February 19, 2021

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 a dedicated 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
k122516	Embletta MPR	Predicate device
k161531	MP50 IntelliVue Patient Monitor	Reference device

Substantial Equivalence

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

Characteristic	Proposed device Onera STS	Predicate device Embletta MPR	Result
Regulation number	21 CFR 868.2375	21 CFR 868.2375	Same
Product code	MNR	MNR	Same
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 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 Embletta MPR is a digital recording device designed to be used under the direction of a physician or trained technician but may be applied by a layperson. The Embletta MPR records multiple physiological parameters from a sleeping patient for the purpose of simultaneous or subsequent display of the parameters. The displayed data assists in the identification of sleep-related medical disorders by trained personnel.	Substantially equivalent
Indications – Patient population	The device is intended to be used for adults.	The Embletta MPR is intended to be used for adult and pediatric (excluding infants and neonatal) studies. The device is not equipped with alarms and is not intended to be used as a monitor.	Substantially equivalent

Characteristic	**Proposed device Onera STS**	**Predicate device Embletta MPR**	**Result**
Indications – Environment	Home and professional environments.	The intended environments include any clean, dry, dust free environment suitable for a patient's relative comfort.	Substantially equivalent
Indications - Limitations	The device is not intended to monitor or diagnose the patient and does not issue alarms	The device does not monitor or diagnose the patient and does not issue any alarms.	Substantially equivalent
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 and mains powered devices.	Similar
Materials	Patches are included with the device and found biocompatible (see summary below)	Patches are not part of the device	Comparable
Duration of Use	8 hours	24 hours	Similar
Measured parameters	EEG (2 channels)	EEG (8 channels)	Comparable
	EOG (2 channels)	EOG (2 channels)	Same
	EMG head (2 channels)	EMG head (3 channels)	Similar
	EMG leg (one leg)	EMG leg (2 legs)	Different Leg movement related sleep disorders can typically be diagnosed by one channel EMG leg
	SpO2 forehead	SpO2 finger	Different SpO2 can be measured in several locations and clinical data shows sufficient accuracy for this location.
	ECG (1 channel)	ECG (1 channel)	Similar

Characteristic	Proposed device Onera STS	Predicate device Embletta MPR	Result
	Respiratory effort (one channel via bioimpedance)	Respiratory effort (2 channels via belt)	Different but comparable with reference device Measuring respiratory effort using bioimpedance is a common technique providing information on relative changes in lung volume similar to using inductive plethysmography on the chest and the abdomen.
	Respiratory flow via nasal cannula	Respiratory flow via nasal cannula	Similar
	Sound pressure	Sound pressure	Similar
Derived parameters	Position (1 channel derived from 3D accelerometer)	Position (1 channel derived from 3D accelerometer)	Similar
	Activity (chest)	Activity (Chest)	Similar
Operating temperature	10°C - 40°C	15°C - 40°C	Similar
Operating relative humidity	10% - 90%	0% - 95%	Similar

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

None of the indicated differences introduces new questions on safety or effectiveness.

Summary of Performance Testing
Performance testing on the Onera STS 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

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.	Negligible irritant
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:
To validate the accuracy of the Onera STS SpO2 sensor, a study was performed using 10 healthy volunteers in a reclined position, in accordance with ISO 80601-2-61:2019 201.12.1.101.2 and Annex EE.2, as recommended by the FDA Guidance for Industry and FDA Staff Pulse Oximeters – Premarket Notification Submissions [510(k)s] .

The population sample was middle-aged (21 - 49), light-to-dark-skinned (Fitzpatrick skin tone type II-VI), and balanced in gender (50% male). The Onera STS SpO2 showed an accuracy of ±3% in the range 70-100%, which is within the pass/fail criteria described in ISO80601-2-61:2019 Clause 201.12.1.101.1.

Comparative sleep study testing:
A clinical validation study was performed to demonstrate equivalence to the Embletta MPR in sleep staging and physiological scoring. The Onera STS and Embletta MPR were concurrently applied to 32 patients undergoing a routine sleep study. The sample population had a well-distributed range of age (23-80 years) and BMI (21 - 37.2), a predominance of males (90.6%), and several common comorbidities (15.6% Hypertension; 12.5% Cardiac Arrythmia; 9.4% Pulmonary diagnosis). Studies were scored blinded by a qualified sleep professional.

There was substantial agreement in scored sleep stages between the Onera STS and Embletta MPR (Cohen's kappa = 0.69). The accuracy, specificity and sensitivity are reported in Table 1, (mean ±

standard deviation). When Stage N1 was removed from the analysis, kappa reached 0.81. Sleep parameters showed a high correlation between the Onera STS and Embletta MPR (Total sleep time 0.77; Sleep efficiency 0.65; Sleep latency 0.95; REM onset latency 0.58; Wake after sleep onset 0.55; Minutes in Stage N1 0.67, N2 0.69, N3 0.65, REM 0.91, and Wake 0.64).

	Accuracy (%)	***Specificity (%)***	***Sensitivity (%)***
Wake	94.08 ± 4.34	97.87 ± 2.00	61.92 ± 21.70
Stage N1	89.62 ± 4.23	95.25 ± 3.02	27.19 ± 12.11
Stage N2	84.69 ± 4.29	81.55 ± 8.05	88.32 ± 4.80
Stage N3	95.60 ± 1.80	98.26 ± 2.05	76.60 ± 18.58
REM	94.70 ± 3.27	95.95 ± 2.66	88.12 ± 14.46

Table 1: Sleep staging accuracy, specificity, and sensitivity between Onera STS and the in-lab PSG.

Conclusion

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