December 8, 2024

Somnomedics GMBH
% Cherita James
Regulatory Consultant
ProPharma Group
1129 20th St NW
Suite 600
Washington, District of Columbia 20036

Re: K240700
Trade/Device Name: HomeSleepTest (HST, HST REM+)
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLV, MNR
Dated: March 14, 2024
Received: March 14, 2024

Dear Cherita James:

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,

FDA 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240700

Device Name
HomeSleepTest (HST, HST REM+)

Indications for Use *(Describe)*
The HomeSleepTest is a non-invasive prescription device for home use with patients suspected to have sleep disorders including sleep-related breathing disorders.
The HomeSleepTest is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. Using three frontal electrodes and one mastoid electrode, the HomeSleepTest records electrical data. In addition, the device records triaxial accelerometer data, ambient light and acoustic data. With help of the ComfortOxyRing, the device records plethysmographic data, as well as SpO2, heart rate and activity data.
The HomeSleepTest calculates and reports to clinicians EEG/EOG/EMG, sleep stages, SpO2, plethysmography, pulse rate and snoring level. Based on this, the HomeSleepTest indices derived parameters, such as autonomic arousal (based on plethysmogram of ring), oxygen desaturation index and hypnogram-derived indices, such as time in each sleep stage, as well as other sleep-related parameters, to aid in determining sleep quality and quantity.
HomeSleepTest data is not intended to be used as the sole or primary basis for diagnosing any sleep disorders, or sleep-related breathing disorders, prescribing treatment, or determining whether additional diagnostic assessment is warranted.
The HomeSleepTest is not intended for use in life-support and monitoring systems. The HomeSleepTest and its accessories are not intended for patients requiring monitoring and intensive care. The HomeSleepTest is a prescription device indicated for adult patients aged 21 years and over.

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.

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510(K) SUMMARY- K240700

The following information is provided as required by 21 CFR § 807.87 for HomeSleepTest 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: SOMNOmedics GmbH
Am Sonnenstuhl 63
Randersacker, Germany D-97236

Contact: Cherita James
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cherita.james@propharmagroup.com

Date Prepared: December 6, 2024

Proprietary Name: HomeSleepTest (HST, HST REM+)

Common Name: Standard Polysomnograph with Electroencephalograph

Regulatory Class: II

Regulation Number & Name: 882.1400 Electroencephalograph

Review Panel: Neurology

Product Codes: OLV, MNR

Predicate Device: SOMNOscreen plus, K201054

Reference Device: Somfit, K231546

Indications for Use: The HomeSleepTest is a non-invasive prescription device for home use with patients suspected to have sleep disorders including sleep-related breathing disorders. The HomeSleepTest is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. Using three frontal electrodes and one mastoid electrode, the HomeSleepTest records electrical data. In addition, the device records triaxial accelerometer data, ambient light and acoustic data. With help of the ComfortOxyRing, the device records plethysmographic data, as well as SpO2, heart rate and activity data.

The HomeSleepTest calculates and reports to clinicians EEG/EOG/EMG, sleep stages, SpO2, plethysmography, pulse rate and snoring level. Based on this, the HomeSleepTest indices derived parameters, such as autonomic arousal (based on plethysmogram of ring), oxygen

desaturation index and hypnogram-derived indices, such as time in each sleep stage, as well as other sleep-related parameters, to aid in determining sleep quality and quantity. HomeSleepTest data is not intended to be used as the sole or primary basis for diagnosing any sleep disorders, or sleep-related breathing disorders, prescribing treatment, or determining whether additional diagnostic assessment is warranted. The HomeSleepTest is not intended for use in life-support and monitoring systems. The HomeSleepTest and its accessories are not intended for patients requiring monitoring and intensive care. The HomeSleepTest is a prescription device indicated for adult patients aged 21 years and over.

Device Description: The HomeSleepTest is used to record vital signs to determine a hypnogram (sleep profile) and sleep parameters that can be helpful in objectively determining sleep quality and quantity.
The HomeSleepTest is available in a standard HomeSleepTest (HST) version and a HomeSleepTest REM+ (HST REM+) version. The only difference between the two basic devices is the measuring point of the outer electrodes on the forehead. HomeSleepTest refers to both versions of the device.

Furthermore, the HomeSleepTest can be used to detect the patient's activity, head position and snoring. A recording with the HomeSleepTest is initialized in the clinic/practice. For this purpose, the patient is given the HomeSleepTest and a tablet to take home. The recording can thus be carried out independently in the home environment. Immediately after recording, the data is automatically transferred to the HST cloud. The physician has access to this data via the HST cloud where they can analyze the data via the HST cloud in DOMINO and generate a report.
A tablet app with video sequences supports the patient in correct application and guides them through the required biocalibration of the system. Once the test is started, all data from the HomeSleepTest is recorded via Bluetooth. The HomeSleepTest records nine signals (3 x frontopolar EEG, 2 x EOG, EMG, snoring, activity and head position). Snoring and snoring rhythm are recorded via the tablet's microphone. Head position, movement and light support information about time in bed (TIB) and other sleep-related parameters.
After completion of the measurement the next morning by the patient, the data is automatically uploaded to the HST cloud where it can be analyzed with help of DOMINO software. After the data has been successfully transferred to the cloud, an exchange with the physician is possible via the feed-back function. It is also possible to release a new

measurement for this patient, so that recordings can be made over several nights to capture variability.
An overview of all measurements is available to the physician in the HST Cloud. A chat area is used for communication between doctor and patient. In the cloud-based evaluation software, both the pre-evaluation and the raw data of the measurement should be analyzed or edited in an AASM compliant manner. A simple report is available immediately after uploading the measurement.
However, the recorded data must still be verified by a physician: for the detailed report (standard report), the measurement is opened in the DOMINO software and scored manually. After evaluation, the standard report is also available in the overview and provides additional information on the various sleep parameters.

Performance Testing Summary: Performance testing was conducted to confirm compliance to device specifications. All functions were verified to operate as designed. Signals recorded by the HomeSleepTest underwent performance testing demonstrating that all signal types being recorded comply with the performance criteria set forth by SOMNOmedics. Testing according to ISO 10993 Parts 5 and 10 of the HST Electrode adhesive demonstrated biocompatibility for the intended use; additional direct contact components including the snap fastener cable, ComfortOxyRing and NuPrep skin paste have been tested and are marketed by OEM manufacturers.

Basic documentation for software design and validation was provided. Cybersecurity assessment including assessment of impact severity and likelihood were provided. The following FDA guidance were conformed to:

- Content of Premarket Submissions for Device Software Functions: June 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: September 2023

Electrical Safety and EMC testing according to IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, and IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment confirm the HomeSleepTest

performs as intended in the proposed operating environments.

Standards

SOMNOmedics GmbH has demonstrated compliance with the following standards for the HomeSleepTest:

Standard
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN 60529:1991+A1:2000+A2:2013 Degree of Degrees of Protection Provided by Enclosures
IEC 62304:2006 + A1:2015 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]

Clinical Performance: Design validation of the sleep-staging capabilities of the HomeSleepTest (HST) was performed by comparing performance to SOMNOscreen plus (PSG configuration) in 20 subjects. This confirmed the device is suitable for the intended use.

Additionally, a study of 30 adult patients was conducted with a primary objective for the validation of parameters measured with the HomeSleepTest in combination with ComfortOxyRing against the gold standard PSG (SOMNOscreen plus, K201054). This includes parameters regarding sleep stages, oxygen desaturation, pulse rate, snoring, and general parameters. The study was designed as a prospective and open validation study.
The measurements of the PSG device and the HST with ComfortOxyRing were evaluated manually according to the current AASM guidelines in random order by a trained and certified scorer. A total of 24563 epochs (excluding epochs with artefacts) from 30 patients were compared. The concordance of the sleep-stages for manually scored epochs is 83.0%, Cohen's kappa is 0.77. The pass criterion of a concordance of 82.0% is achieved.

Sleep Parameters were evaluated in a comparative analysis of sleep stages and therefore key sleep parameters performance was compared between PSG and HST.

Lights off/on was set equal for both devices based on the video of the PSG recording.

Total Sleep Time (TST) measured with PSG and HST showed only minor differences in TST

between the devices. The sustained sleep efficiency of 81.85% for PSG and 80.40% for HST showed a difference of 1.45%.

Sleep latency, REM latency, Sleep Period Time and Wake After Sleep Onset also showed only minor time differences between the subject and predicate device.

Comparison of sleep stages in relation to the parameter of Time in Bed (TIB) were evaluated.

Comparison of different sleep stages as % TIB showed that wake, REM, N1, N2, N3 all meet the acceptance criteria of + 10%. Manually scored arousal index for both the subject and predicate devices also met the acceptance criteria.

The following oxygen desaturation parameters also met acceptance criteria:

- Number of Desaturations total, 90%, and <80%
- ODI
- Minimal and average SpO2
- Baseline O2 Saturation
- SpO2 time<90%
- Largest, average and longest desaturation
- Average minimum desaturation
- Deepest desaturation, sum of all desaturations
- Artifact

Comparison of the average pulse rate obtained for PSG and HST demonstrated minimal differences.

Snoring parameters including snore number, index, absolute snore and snore for total sleep time met acceptance criteria. General parameters for subject position (upright or not upright) provided comparable results.

In the second step the pre-evaluation (automated analysis) of the HST sleep stages is compared to the manually scored measurements of the reference PSG device, A total of 24042 epochs (excluding epochs with artefacts) from 30 patients were compared. The concordance was 53.7%, Cohen's kappa was 0.40. For the pre-evaluation of the HST, the pass criterion of a concordance of 50.0% was achieved.

The DOMINO Scorer Manager was used to evaluate the interrater variability. The HST sleep stages were scored by two scorers. The agreement over all 30 HST measurements between scorer 1 and scorer 2 was 71.3%. Therefore, the pass criterion of an agreement above 70.0% was achieved.

The results indicate strong consistency between manually-scored PSG and manually-scored HST recordings across key sleep parameters.

Substantial Equivalence Comparison

Features / Technical Information	**HomeSleepTest (REM+) Subject device**	**SOMNOscreen® plus Predicate device**	**Somfit® by Compumedics Limited Reference device**	**Discussion of difference/Substantial Equivalence**
Product Code	**OLV, MNR**	**OLV, MNR**	**MNR, OMC**	
K-Number	**K240700**	**K201054**	**K231546**	
Indications for Use / Intended Use	The HomeSleepTest is a non-invasive prescription device for home use with patients suspected to have sleep disorders including sleep-related breathing disorders. The HomeSleepTest is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. Using three frontal electrodes and one mastoid electrode, the HomeSleepTest records electrical data. In addition, the device records triaxial accelerometer data, ambient light and acoustic data. With help of the ComfortOxyRing, the device records plethysmographic data, as well as SpO2, heart rate and activity data. The HomeSleepTest calculates and reports to clinicians EEG/EOG/EMG, sleep stages, SpO2, plethysmography, pulse rate and snoring level. Based on this, the HomeSleepTest indices derived parameters, such as autonomic arousal (based on plethysmogram of ring), oxygen desaturation index and hypnogram-derived indices, such as time in each sleep stage, as	**T**he SOMNOscreen® plus is a non-life-supporting portable physiological signal recording device intended to be used for testing adults and children (age 2 to 12 years)/adolescents (age 12 and above) suspected of having sleep-related breathing disorders. The SOMNOscreen® plus is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders. The device is NOT designed to be used in a Life Support situation. The device is not designed for use on patients with cardiac pacemakers.	The Somfit system is a non-invasive prescription device for home use with patients suspected to have sleep-related breathing disorders. The Somfit is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. The Somfit system acquires electrical data from three frontal electrodes, tri-axial accelerometer data, acoustical and plethysmographic data. The Somfit calculates and reports to clinicians EEG/EOG channels, Sleep Stages, SpO2, Peripheral Arterial Tonometry (PAT) signal, pulse rate, and snoring level. The Somfit calculates and reports to clinicians derived parameters such as PAT-derived Apnea Hypopnea Index, Obstructive Desaturation Index; and hypnogram- derived indices such as time in each sleep	SOMNOscreen® plus is used as the predicate device. Both the HomeSleepTest and SOMNOscreen® plus help the physician to diagnose sleep related breathing disorders. The same signals are used and the same DOMINO software for analyzing the measurement is part of the system. The patient population of the HST is included in the patient population of the SOMNOscreen® plus. Somfit is used as a reference device for the same indication for use. Both HST and Somfit are intended for adult populations.

	well as other sleep-related parameters, to aid in determining sleep quality and quantity. HomeSleepTest data is not intended to be used as the sole or primary basis for diagnosing any sleep disorders, or sleep-related breathing disorders, prescribing treatment, or determining whether additional diagnostic assessment is warranted. The HomeSleepTest is not intended for use in life-support and monitoring systems. The HomeSleepTest and its accessories are not intended for patients requiring monitoring and intensive care. The HomeSleepTest is a prescription device indicated for adult patients aged 21 years and over.		stage. Somfit data is not intended to be used as the sole or primary basis for diagnosing any sleep- related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted. The Somfit is not intended for use as life support equipment, for example vital signs monitoring in intensive care unit. The Somfit is a prescription device indicated for adult patients aged 21 years and over.	
Type of Use	Prescription Use Only	Prescription Use Only	Prescription Use Only	Equivalent
Patient population	Adults – 21 years and above	Adults and children (age 2 to 12 years)/adolescents (age 12 and above)	Adults – 21 years and above	Equivalent to Somfit predicate device
Usage Environment	Home and further possible applications are to be found in	N/A	Home	HomeSleepTest (REM+) and Somfit® are intended for home use. In addition

Features / Technical Information	**HomeSleepTest (REM+) Subject device**	**SOMNOscreen® plus Predicate device**	**Somfit® by Compumedics Limited Reference device**	**Discussion of difference/Substantial Equivalence**
	clinics and physicians' practices with relevant diagnostic potential.			the HomeSleepTest (REM+) can be used in physicians' practices. Difference does not affect safety or effectiveness.
Mass	28 g (with battery)	220 g (with battery)	≤ 15g (with battery)	The HomeSleepTest (REM+) is lighter than the SOMNOscreen plus and slightly heavier than the Somfit®. Difference does not affect safety or effectiveness.
Dimensions	43 mm x 36,5 mm x 10 mm (Diameter: 56,4)	140 mm x 70 mm x 28 mm	43 mm x 43 mm x 19.7 mm (device + charging cradle)	The HomeSleepTest (REM+) is slightly smaller than the predicates. Difference does not affect safety or effectiveness.
Biocompatibility	Overnight use on intact skin	Overnight use on intact skin	Overnight use on intact skin	Equivalent
Materials	Adhesive (wet/hydrogel) electrodes PC-PBT	N/A	Adhesive (wet) electrode ABS Plastic	The discussion of biocompatibility can be found in the Substantial Equivalence Discussion Document. Difference does not affect safety or effectiveness.
Portable	Yes	Yes	Yes	Equivalent
Sold Sterile or Sterilization Required	No	No	No	Equivalent
Energy Source	1x 240 mAh 3.7 V Li-Ion battery	1 x 2800 mAh 3.7 V Li-Ion battery	1 x 120 mAh 3.7 V Li-Ion battery	A more powerful battery is integrated in HomeSleepTest (REM+) than Somfit. Difference does not affect safety or effectiveness.
Battery Life	Recording with fully charged battery: 36 hours continuous recording	Recording with fully charged battery: 23 hours continuous recording	On standby/idle mode: 48 hours (2 days) Recording: 16 hours continuous recording	The HomeSleepTest (REM+) battery life allows for longer continuous recording. Difference does not affect safety or effectiveness.
Electronic Sensors	Photodiode Analog front end for SpO2 Microphone Accelerometer Biosignal front end incl EEG amplification	Photodiode Oximeter Microphone Accelerometer Biosignal front end incl EEG amplification	Photodiode Oximeter front end (AFE4404) Microphone Accelerometer EEG Amplification	Equivalent sensors are used to measure signal in HST and SOMNOscreen® plus. Analog front end for SpO2 is cleared within the ComfortOxyRing.

Features / Technical Information	**HomeSleepTest (REM+) Subject device**	**SOMNOscreen® plus Predicate device**	**Somfit® by Compumedics Limited Reference device**	**Discussion of difference/Substantial Equivalence**
	Light sensor	Light sensor **(Only relevant electronic sensors for this comparison are listed)**		Difference does not affect safety or effectiveness.
Pulse Oximeter	ComfortOxyRing (K221361)	Soft Silicone Finger Sensor for Pulse Oximeter for pediatric / adults	Pulse rate data was obtained from Nonin and Masimo reference oximeters during a controlled desaturation study. Two hundred and thirty-seven pulse rate samples were obtained from 12 healthy patients, and analysed using the statistical methods mandated by ISO 80601-2-61. The root-mean square error was found to be 1.91 BPM with a mean difference of 0.017 BPM between the Somfit and Masimo oximeters. The root-mean square error was found to be 1.81 BPM with a mean difference of 0.00 BPM between the Somfit and Nellcor oximeters. Potential sources of error may include inadequate synchronization between devices, since oximeters provide a range of data update rates, and were placed at differing anatomical locations, as well as additional patient motion	Other method, same signals. ComfortOxyRing (The circul™ pro Ring) has the appropriate intended use for use with the HST. K221361: The circul™ pro Ring is a wireless, non-invasive, and stand-alone pulse oximeter intended to be used for spot-check and/ or continuous data collection of oxygen saturation of arterial hemoglobin (Sp02) and pulse rate (PR) through the index finger in adult patients. It can be used in hospitals and home environments for up to twelve hours in non-motion and well perfused conditions. It is not intended for single-use and out-of-hospital transport use and does not have alarms. Difference does not affect safety or effectiveness.

Features / Technical Information	**HomeSleepTest (REM+) Subject device**	**SOMNOscreen® plus Predicate device**	**Somfit® by Compumedics Limited Reference device**	**Discussion of difference/Substantial Equivalence**
			associated with the condition of profound hypoxemia during wake. In addition to testing against a pulse rate simulator, this clinical performance data supports the claim of substantial equivalence and satisfies validation requirements of ISO 80601-2-61	
Analysis Software	DOMINO	DOMINO	Sleep Profiler	Equivalent to primary predicate device
Channel	Plethysmography Oxygen saturation EEG/EOG/EMG Sound for snore detection Activity Position	Plethysmogram Oxygen saturation EEG/EOG/EMG Sound for snore detection Activity Position **(Only relevant channels for this comparison are listed)**	PAT Oximetry EEG Snoring Motion	Same channels already used within SOMNOscreen® plus.
Analysis Output	Sleep stages Snoring ODI Pulse rate Position	Sleep stages Snoring ODI Pulse rate Position (**Only relevant analysis output for this comparison is listed)**	Sleep stages Snoring Level ODI pAHI	Uses same output than SOMNOscreen plus. The analysis output is scored and evaluated within the analysis Software DOMINO of the SOMNOscreen® plus. Substantially Equivalent
Application Site	Forehead	N/A	Forehead	Equivalent to predicate device
Device Visual Indicator	LED on Device, mobile application	Alphanumeric display	Green and blue LEDs on device, mobile application	Equivalent to predicate device
User Control	Start/stop button on mobile application	Start/Stop via menu on display or pre-initialized automatic start	Start/stop button on mobile application	Equivalent to predicate device

Features / Technical Information	**HomeSleepTest (REM+) Subject device**	**SOMNOscreen® plus Predicate device**	**Somfit® by Compumedics Limited Reference device**	**Discussion of difference/Substantial Equivalence**
Data Collection	Data is transferred from the device to the tablet via Bluetooth. After the measurement is completed, the data is securely uploaded to the HST Cloud. Furthermore, the HST Cloud preprocesses the data with DOMINO and the results are stored in a secure database inside the Cloud. The user can later further analyze the data with DOMINO inside their user account.	Data is via a Docking station transferred to the physicians PC for storage and analysis.	Study data is wirelessly transferred through Bluetooth from the device to a mobile application. Data is then uploaded into a secure Cloud and to Nexus360 web server for storage and analysis.	HST uses the same Data Collection and transfer as the Somfit®. Only the Storage Device is different. Difference does not affect safety or effectiveness.

Conclusion: The subject and primary predicate device are both non-invasive prescription devices for home use with measuring system for recording of physiological signals. They assist the physician in diagnosing sleep disorders, including sleep-related breathing disorders.

There is no relevant difference in the indications for use or the intended use of the subject device and the primary predicate device. The subject device has the similar principles of operation and technical characteristics as the previously cleared primary and reference predicates. The subject device fulfils the requirements of IEC 60601-1-11 for home use. Patient contacting components have been evaluated for biocompatibility.

The differences do not raise new issues regarding safety or effectiveness.

The HomeSleepTest is substantially equivalent to the predicate device.