August 28, 2025

Compumedics Limited
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, NJ 07059

Re: K252383
Trade/Device Name: Somfit D
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing frequency monitor
Regulatory Class: Class II
Product Code: MNR, OMC
Dated: July 30, 2025
Received: July 31, 2025

Dear Dave Yungvirt:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252383

Device Name
Somfit D

Indications for Use *(Describe)*
The Somfit D is a single-use, non-invasive prescription device for home use with patients suspected to have sleep-related breathing disorders. The Somfit D is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. The Somfit D system acquires electrical data from three frontal electrodes, tri-axial accelerometer data, acoustical and plethysmographic data. The Somfit D calculates and reports to clinicians EEG/EOG channels, Sleep Stages, SpO2, Peripheral Arterial Tonometry signal, pulse rate, and snoring level. The Somfit D calculates and reports to clinicians derived parameters such as Peripheral Arterial Tonometry-derived Apnea Hypopnea Index, Obstructive Desaturation Index; and hypnogram-derived indices such as time in each sleep stage. Somfit D 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 D is not intended for use as life support equipment, for example vital signs monitoring in intensive care unit. The Somfit D 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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K252383 Somfit D 510(k) Summary

Device Name: Somfit D

The following 510(k) summary is being submitted in accordance with 21 CFR 807.92.

Submission Details

Applicant Information:

Submitter: Compumedics Limited
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Email: jjoseph@compumedics.com.au

Submission Prepared: 05th Jun 2025

Subject Device Information:

Trade name: Somfit D
Common name: Somfit D
Product code: MNR, OMC
Classification Names: Ventilatory Effort Recorder
Panel: Anesthesiology
Device class: II
Regulation numbers: 21 CFR 868.2375

Predicate Device Information

Trade Name: Somfit
Manufacturer: Compumedics Ltd.
510(k) number: K231546
510(k) Decision Date: 30th Nov 2023
Classification: Ventilatory Effort Recorder
Product code: MNR, OMC
Device class: II
Regulation numbers: 21 CFR 868.2375

Device Description

The Somfit D is a home-based sleep monitoring device which records signals from the patient's forehead. Somfit D is a wearable, low voltage, battery operated device which is attached to subject forehead via a self-adhesive and disposable skin electrode patch. The electrodes are placed on the anterior Prefrontal cortex (PFC) at the Fp1 and Fp2 positions according to the 10/20 EEG system. The device allows for recording of two frontal EEG signals, pulse rate, SPO2, PAT, PPG, motion, and snore. Somfit D uses a mobile phone application to acquire data wirelessly via Bluetooth BLE technology, then transfer into a secure cloud, for management, storage and post-processing. The software reports measured parameters in a format compatible with the American Academy of Sleep Medicine guidelines, including sleep time, ODI, pAHI and conventional graphical displays such as a hypnogram.

Intended Use / Indications For Use

The Somfit D is a non-invasive prescription device for home use with patients suspected to have sleep-related breathing disorders. The Somfit D is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. The Somfit D system acquires electrical data from three frontal electrodes, tri-axial accelerometer data, acoustic and plethysmographic data. The Somfit D calculates and reports to clinicians EEG channels, Sleep Stages, *SpO2*, Peripheral Arterial Tonometry (PAT) signal, pulse rate, and snoring level. The Somfit D 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 stage. Somfit D 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 D is not intended for use as life support equipment, for example vital signs monitoring in intensive care unit. The Somfit D is a prescription device indicated for adult patients aged 21 years and over.

Comparison of Intended Use

The Somfit D and Somfit have the same intended use. Both devices are prescription-only and intended for use in the patient's home environment under the direction of a physician. The Somfit D measures physiological signals from MEMS sensors including EEG, two-channel PPG, accelerometry and microphone data acquisition. These are processed to present the clinician with waveform display of EEG, PAT, SpO2, pulse rate, motion, snore sounds. The sleep staging and PAT algorithm generate and report clinically relevant data such such as the hypnogram and pAHI. This is the same as Somfit . Based on over 30 years of experience designing and manufacturing sleep assessment devices, Compumedics Ltd does not believe claims should be made regarding the diagnosis of central apnea from PAT-based devices, as direct measurement of airflow is critical which is not provided by either Somfit D or Somfit.

Both Somfit D and Somfit are intended to provide the physician with data that may aid in diagnosis. They do not provide a diagnosis themselves, nor are they intended to be the sole factor in a diagnosis. The interpretation of data is reserved for suitably qualified clinicians, and both devices are marketed as prescription only and should be only used under the direction of a physician. None of the devices are intended for use in an intensive care unit, or emergency care environment. Based on the comparison of

Somfit D indications for use with Somfit, it was determined that Somfit D has the same intended use as its predicate device.

Comparison of Technological Characteristics

The Somfit D uses the same fundamental technology and principles of operation as the Somfit. Both devices are low power battery-operated ventilatory effort recorders utilizing oximeters, tri-axial accelerometers, microphone, and PAT-based technology. Both Somfit & Somfit D are notably worn on forehead as opposed to the wrist and uses an EEG sensor to directly measure brain activity and determine sleep stage. The Somfit data is acquired using a mobile application which uploads data to the Nexus360 Web Server for automatic analysis and review by physician. Further analysis of technological characteristics is available in the Substantial Equivalence discussion. The Somfit uses the same underlying principles of operation as the Somfit, and design differences do not raise questions of safety or effectiveness.

A detailed comparison is provided through evaluation of design features such as energy source, principles of operation, materials, and user interface. Further comparison and analysis is available in Somfit D Substantial Equivalence Discussion.

	Predicate Device Somfit (K231546)	**New Device Somfit D**	**Comments**
Manufacturer	Compumedics Limited	Compumedics Limited	
Device Classification	MNR OMC	MNR OMC	Same as predicate device
FDA Classification	Class II	Class II	Same as predicate device
Indications for Use	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, acoustic and plethysmographic data. The ***Somfit*** calculates and reports to clinicians EEG channels, Sleep Stages, *SpO2*,	The ***Somfit*** D system is a single-use, non-invasive prescription device for home use with patients suspected to have sleep-related breathing disorders. The ***Somfit D*** is a diagnostic aid for the detection of sleep-related breathing disorders, sleep staging (REM, N1, N2, N3, Wake), and snoring level. The ***Somfit D*** system acquires electrical data from three frontal electrodes, tri-axial accelerometer data, acoustic and plethysmographic data. The ***Somfit D*** calculates and reports to clinicians EEG channels, Sleep Stages, *SpO2*, Peripheral Arterial Tonometry	Similar, the difference being Somfit D is intended for single-use applications and is powered by a non-rechargeable battery.

	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 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.	(PAT) signal, pulse rate, and snoring level. The Somfit D 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 stage. ***Somfit D*** 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 D*** is not intended for use as life support equipment, for example vital signs monitoring in intensive care unit. The ***Somfit D*** is a prescription device indicated for adult patients aged 21 years and over.	
Type of Use	Prescription Use Only	Prescription Use Only	Identical
Patient population	Adults – 21 years and above	Adults – 21 years and above	Identical
Usage Environment	Home	Home	Identical
Mass	≤ 15g (with battery)	≤ 15g (with battery)	Similar
Dimensions	43mm x 43 mm x 19.7 mm (device + charging cradle)	35mm x 12.85 mm	Similar
Biocompatibility	Overnight use on intact skin	Overnight use on intact skin	Identical
Materials	Adhesive (wet) electrode ABS Plastic	Adhesive (wet) electrode ABS Plastic	Identical

Sold Sterile or Sterilization Required	No	No	Identical
Energy Source	1 x 120mAh 3.7V Li-Ion battery	1 x 225 mAh 3.0V Li-MnO2 battery (EVE CR2032)	Similar, both are battery-powered
Battery Life	Hours of Use: On standby/idle mode: 48 hours (2 days) Recording: 16 hours continuous recording	Hours of use: On standby/idle mode: 24 hours (1 day) Recording: 9 hours continuous recording	Similar, slightly lower than predicate device.
Microprocessor	ARM (TI)	ARM (TI)	Identical
Electronic Sensors	Photodiode Oximeter front end (AFE4404) Microphone Accelerometer EEG Amplification	Photodiode Oximeter front end (AFE4404) Microphone Accelerometer EEG Amplification	Identical
Channel	PAT Pulse Rate Oximetry EEG Snoring Motion	PAT Pulse Rate Oximetry EEG Snoring Motion	Identical
Analysis Output	pAHI Sleep stages Snoring Level ODI	pAHI Sleep stages Snoring Level ODI	Identical
Application Site	Forehead	Forehead	Identical
Device Visual Indicator	Green and blue LEDs on device, mobile application	Green LED on device, mobile application	Similar
User Control	Start/stop button on mobile application	Start/stop button on mobile application	Identical
Data Collection	Study data is wirelessly transferred through Bluetooth from the device to a mobile	Study data is wirelessly transferred through Bluetooth from the device to a mobile	Identical

	application. Data is then uploaded to Nexus360 web server for storage and analysis.	application. Data is then uploaded to Nexus360 web server for storage and analysis.	

Table 1: Tabular Comparison with Predicate device

Non-Clinical Performance Data

Both the Somfit (already approved under K231546) and Somfit D have the same energy source which is low volt (<4V) battery making them identical in electrical safety and they share identical wireless systems making their EMC conditions are identical, and they have same EEG and PPG data acquisition systems making their safety and performance are identical in that aspect. Testing activities were conducted on Somfit which was already approved under K231546, applies to Somfit D which is the disposable version of Somfit that did not raise any issues of safety and effectiveness. These included:

- Electrical Safety Testing as per IEC 60601-1:2005 (Third Edition) + COR1:2006 + COR2:2007 + A1:2012
- Electromagnetic Compatibility Testing as per IEC 60601-1-2:2014, EN 60601-1-2:2015, and modification by the listed particular and collateral standards
- Home Healthcare Environmental testing as per IEC 60601-1-11:2015
- Electroencephalograph safety and performance testing as per IEC 60601-2-26:2012
- Pulse oximeter safety and performance testing as per ISO 80601-2-61:2011 including tests with functional simulator
- Hardware bench testing to verify electrical parameters and design specifications
- Software testing to verify functional requirements and system integration

Since the only difference between the Somfit and the Somfit D is the use of a non-rechargeable battery, additional verification testing—such as hardware bench testing and biocompatibility evaluation—is not required. All other components and functionalities remain unchanged. The only new verification document included in this submission is the IEC 60086-4 test report for the Somfit D's CR2032 battery, which addresses safety requirements for single use lithium batteries.

The test methods are in line with international standards where they exist, and other FDA-cleared devices where outputs have not yet been standardized.

The Somfit Hazard and Risk Analysis identifies a full range of hazards including those associated with electrical safety, electromagnetic compatibility, data quality, environmental conditions, biocompatibility, usability, software, cybersecurity, and device outputs.

Clinical Performance

To further demonstrate the safety, effectiveness, and substantial equivalence of the Somfit D, multiple clinical studies were conducted to validate the performance of the predicate device, Somfit. These studies included clinical validation of oximeter performance, home sleep apnea testing (HSAT), pAHI (predicted

Apnea-Hypopnea Index), ODI (Oxygen Desaturation Index), and sleep staging. All validations were performed using the Somfit device, which was previously cleared under 510(k) number K231546. Since the only difference between the Somfit and the Somfit D is the non-rechargeable battery, the performance of the Somfit D is equivalent to that of the cleared Somfit device.

Oximeter Validation – Controlled Desaturation Study
A formal controlled desaturation study was conducted in accordance with ISO 80601-2-61 at Hypoxia Lab. Full Somfit data (K231546) already submitted and approved which includes AI441 Pulse Oximeter Testing Report and AI442 Somfit Oximeter and Heart Rate Performance Evaluation in VOL_020_Performance Testing – Clinical of the predicate device, Somfit's data acquisition system is identical to Somfit D.
Based on the above statement, supporting the claim of substantial equivalence, Somfit D has the same pulse oximeter as Somfit which provides identical performance.

Home Sleep Apnea Test Validation – Multi-Site Clinical Study
A clinical study was conducted to obtain clinical data for the purpose of the predicate device Somfit (K231546), already submitted and approved, which is equivalent to Somfit D as they have same EEG acquisition systems which measure parameters such as PAT-derived AHI (pAHI) and sleep stage concordance.

pAHI
The predicate device Somfit's pAHI (K231546) study was already submitted and recognized for providing meaningful validation of Somfit as an HSAT device which is identical to Somfit D.

ODI
The predicate device Somfit's ODI (K231546) study was already submitted and recognized for providing meaningful validation of Somfit as an HSAT device which is identical to Somfit D.

Sleep Staging
The predicate device Somfit's Sleep Staging (K231546) study was already submitted and recognized for providing meaningful validation of Somfit as an HSAT device which is identical to Somfit D.

Conclusion

Compumedics Ltd. considers the Somfit D to be substantially equivalent to its predicate device the Somfit. The intended use as an HSAT device are identical. The fundamental principles of operation are the same, and where differences exist they have been discussed. There are no questions of safety and effectiveness, and substantial equivalence is supported by extensive performance testing and clinical data.