April 17, 2026

Somnetics International, Inc (DBA Transcend Inc)
William Brown
CEO
103 Osborne Road NE
Fridley, Minnesota 55432

Re: K252338
Trade/Device Name: MySleepDash
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 28, 2025
Received: July 28, 2025

Dear William Brown:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.04.17 22:02:16 -04'00'

For

Rachana Visaria
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K252338

Device Name
MySleepDash Mobile Application

Indications for Use *(Describe)*
The MySleepDash Mobile Application software is intended to be used in conjunction with Transcend Continuous Positive Airway Pressure (CPAP) devices to support individuals diagnosed with obstructive sleep apnea (OSA). The application enables users to view therapy data, monitor device usage, and adjust comfort settings. The application is also intended for healthcare professionals to configure Transcend CPAP device settings. It does not provide automated diagnosis or treatment recommendations and should be used in conjunction with professional medical oversight.

Transcend CPAP devices are intended for use in adults adults weighing over 66 pounds (30 kg). These devices are intended for home and hospital/institutional use.

This mobile health application is for prescription use only (Rx Only).

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 – MySleepDash Mobile Application

Date of Submission:	04-August-2025
Company Name/Owner:	Somnetics International, Inc. (DBA Transcend Inc.)
Official Contact:	Mr. William Brown CEO Transcend Inc. 103 Osborne Road NE Fridley, MN 55432 USA
Trade/Device Name:	MySleepDash Mobile Application
Device Common Name:	Ventilator, Non-Continuous (Respirator)
Regulation Name:	Noncontinuous ventilator (IPPB)
Classification:	II
Classification Name:	Noncontinuous ventilator (IPPB)
Product Code:	BZD
Predicate Device:	Monte Carlo (mobile application in the Menai System) K160836
Submission Reason:	New Device

Device Description:
The MySleepDash Mobile Application is a cross-platform mobile health app designed to support users of Transcend CPAP devices in managing their sleep apnea therapy. The app enables patients to wirelessly connect to their CPAP device via Bluetooth Low Energy (BLE), allowing for seamless data synchronization, review of therapy usage, and basic device configuration. Through a user-friendly interface the application provides intuitive access to usage summaries, compliance reports, and sleep metrics.

Beyond its mobile interface, MySleepDash integrates with a cloud platform, enabling secure storage and remote access to patient data. Users can operate the app offline to view previously synced data, while clinicians benefit from cloud-based access to monitor adherence and therapy effectiveness.

Indications for Use:
The MySleepDash Mobile Application software is intended to be used in conjunction with Transcend Continuous Positive Airway Pressure (CPAP) devices to support individuals diagnosed with obstructive sleep apnea (OSA). The application enables users to view therapy data, monitor device usage, and adjust comfort settings. The application is also intended for healthcare professionals to configure Transcend CPAP device settings. It does not provide automated diagnosis or treatment recommendations and should be used in conjunction with professional medical oversight.

Transcend CPAP devices are intended for use in adults weighing over 66 pounds (30 kg). These devices are intended for home and hospital/institutional use.

This mobile health application is for prescription use only (Rx Only).

Substantial Equivalence Comparison:

Item	MySleepDash Mobile Application	Predicate: ResMed Monte Carlo (K160836)	Comparison Summary
510(k) Number	K252338	K160836	N/A
Product Code	BZD	BZD	Identical
Regulation Number	868.5905	868.5905	Identical
Regulation Name	Ventilator, non-continuous (respiratory)	Ventilator, non-continuous (respiratory)	Identical
Device Type	Mobile software accessory to CPAP device	Mobile software accessory to CPAP device	Identical
Indications for Use	The MySleepDash Mobile Application software is intended to be used in conjunction with Transcend Continuous Positive Airway Pressure (CPAP) devices to support individuals diagnosed with obstructive sleep apnea (OSA). The application enables users to view therapy data, monitor device usage, and adjust comfort settings. The application is also intended for healthcare professionals to configure Transcend CPAP device settings. It does not provide automated diagnosis or treatment recommendations and should be used in conjunction with professional medical oversight. Transcend CPAP devices are intended for use in adults weighing over 66 pounds (30 kg). These devices are intended for	Excerpted from Indications from Use Statement: Monte Carlo is a mobile application for patients to remotely operate a prescribed compatible ResMed machine and transfer, analyze and display usage and therapeutic information. Monte Carlo also allows healthcare professionals to remotely configure compatible OSA therapy devices.	The intended uses are substantially equivalent. Both applications are mobile software accessories that support CPAP therapy for OSA by enabling therapy data review, user engagement and device interaction.

	home and hospital/institutional use.		
Intended Population of Use	Adult	Adult	Identical
Environment of Use	Home and hospital	Home and hospital	Identical
Therapy Data Display	• Usage hours • Mask Leak • Events Per Hour (AHI) • Therapy summaries • Sleep score (non-diagnostic summary metric) • Ramp starting pressure • Ramp duration • EZEX setting • Mask Removed • Display of device settings	• Usage hours • Mask seal indicators • Events per hour • Mask-off events • Therapy summaries	The MySleepDash Mobile Application and the Monte Carlo provide substantially equivalent therapy data display functionality. Both applications provide therapy data visualization and summary metrics to support patient engagement and adherence. Differences in presentation (e.g., sleep score or display of settings) do not impact intended use or raise new questions of safety or effectiveness.
Compliance Manager	Provides daily/weekly/monthly summaries; primary data summaries (usage, leak, pressure, AHI events per hour, therapy settings); sleep score; mask removals; mobile viewing; export to PDF/email. No device data stored on phone; data uploaded to cloud	Provides daily therapy insights through the myAir score, which is calculated based on usage hours, mask seal quality, events per hour, and mask-off events. The application displays therapy trends and provides coaching messages intended to support adherence.	The MySleepDash Mobile Application and the Monte Carlo provide substantially equivalent compliance and therapy summary functionality.

Communication	Serial character command request/response protocol via Bluetooth Low Energy (BLE) running a Serial Port Profile.	The application communicates with compatible ResMed CPAP devices using Bluetooth wireless technology to retrieve therapy data and support application functionality.	The MySleepDash Mobile Application and the Monte Carlo provide substantially equivalent wireless communication functionality with compatible CPAP devices.
Data Processing and Storage	Data is collected from the CPAP device via BLE, displayed on the mobile device and transmitted to a secure cloud platform via encrypted HTTPS for storage. Limited functionality is available offline; cloud connectivity enables full functionality.	Data is collected from the CPAP device and synchronized to a cloud-based platform, where it is stored and accessed via mobile or web interfaces for therapy monitoring and compliance tracking.	Both devices utilize mobile-to-cloud architectures for data storage and access. Data flow, storage, and access models are substantially equivalent and do not raise new questions of safety or effectiveness.
Language Support	English, French, Spanish, Japanese, Korean	English and Spanish.	Differences in language support do not affect the intended use or safety, and the applications are substantially equivalent in this regard.
Firmware Update	Provides ability to update the firmware if device version is older than latest release.	Publicly available documentation does not explicitly describe firmware update capability for the connected CPAP device initiated or managed through the mobile application.	Differences in firmware update capabilities do not affect intended use, and the applications are substantially equivalent.

Host Platform	Android or iOS mobile device	The Monte Carlo application is available on iOS and Android mobile platforms. In addition, therapy data may be accessed through a web-based interface using a supported internet browser, depending on device compatibility and regional availability.	The MySleepDash Mobile Application and the Monte Carlo are substantially equivalent with respect to supported host platforms.
Cybersecurity	BLE Security Mode 1 Level 2, password complexity and length requirements, SHA-256 encrypted data storage in Azure, short-lived scoped JWTs with revocation, centralized logging, checksum-verified signed updates, restricted cloud IAM roles with secrets management, role-based access control via JWTs, secure backend logic, software composition, analysis for dependencies, API rate limiting, and secure session tokens with expiration and revocation.	The Monte Carlo uses encrypted Bluetooth pairing, application-level encryption for data transmission, and encryption of stored therapy data. General user-facing security guidance is provided for account and device security, while detailed backend security controls are not publicly disclosed.	The MySleepDash Mobile Application and the Monte Carlo are substantially equivalent with respect to cybersecurity functionality.
Software Level of Documentation	Basic	Basic	Identical
Software and Cybersecurity Documentation	Developed and documented in accordance with FDA guidance, including "Content of Premarket Submissions for Device Software Functions" (2023) and "Cybersecurity in Medical Devices" (2023). Includes software architecture documentation, verification and validation testing, risk	Publicly available information indicates use of encrypted communication and general cybersecurity controls; however, detailed documentation is not publicly disclosed in predicate materials.	MySleepDash demonstrates software lifecycle and cybersecurity documentation consistent with current FDA expectations. Differences in documentation transparency do not impact device functionality or safety and do not raise new questions of safety or

	management, SBOM and cybersecurity controls such as encryption (BLE and HTTPS), authentication, logging, and access control.		effectiveness.
Comfort Settings Control	Allows adjustment of user-accessible comfort settings only, including AirRelief, GentleRise Pressure, and GentleRise Duration.	Allows user interaction with comfort-related features and therapy engagement tools.	Both devices provide limited user adjustment of comfort settings while restricting access to therapy-critical parameters. These controls ensure safe use and do not alter the intended therapy. Differences do not raise new questions of safety or effectiveness.
Therapy Setting Control	Therapy pressure settings (minimum, maximum, starting pressure) are visible but not user-adjustable and are restricted to clinician configuration. Changes require BLE connection and physical scanning of the QR code on the device.	Therapy parameters are prescribed and controlled within the CPAP system and are not freely modifiable by the patient through the application. Changes require BLE connection and physical scanning of QR code or entering 4-digit QR code on the device.	Both applications restrict user access to therapy-critical parameters and ensure the prescribed therapy settings are controlled within the CPAP system.

The MySleepDash Mobile Application and the predicate device both function as mobile software accessories to CPAP devices, providing therapy data visualization, compliance tracking, and wireless communication with the device. Both systems limit user interaction to comfort-related settings while maintaining control of therapy-critical parameters within the prescribed device configuration. Additionally, both devices utilize mobile applications with cloud-based data storage. MySleepDash has been developed in accordance with current FDA software and cybersecurity guidance, with comprehensive documentation supporting software verification, validation and risk management. These similarities in functionality, architecture and controls support a determination of substantial equivalence and do not raise new questions of safety or effectiveness.

Substantial Equivalence Conclusion:

The MySleepDash Mobile Application has the same intended use, similar technological characteristics, and substantially equivalent functional performance compared to the predicate device (K160836). Both applications function as mobile software accessories to CPAP devices, providing therapy data display,

compliance and therapy summaries, wireless communication with compatible devices, and appropriate cybersecurity controls. Any minor differences in implementation do not raise new questions of safety or effectiveness. Therefore, the MySleepDash Mobile Application is substantially equivalent to the Monte Carlo predicate device.

Non-Clinical and Clinical Tests Summary:

The MySleepDash Mobile Application underwent comprehensive risk management, nonclinical testing, and usability validation in accordance with applicable standards and guidance.

Non-clinical verification and validation testing completed for device software functions demonstrated that the device met all intended performance requirements. Testing included:

- Software verification and validation, including non-functional requirements and end-to-end functional testing.

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

Risk management activities included evaluation of use-related and cybersecurity risks. A total of 95 use-related risks and 56 design risks across 11 software modules were identified and mitigated through design controls. Residual risks were reduced to acceptable levels, with the highest residual risks associated with user-dependent factors (e.g., login errors, network instability) and controlled through interface design, access restrictions, and user notifications. Cybersecurity risk assessment evaluated 12 threat scenarios; all residual risks were reduced to acceptable levels, including a justified residual risk related to BLE pairing mitigated through physical proximity requirements and encryption. No residual risks are expected to result in serious harm, and the overall benefit-risk profile is considered favorable.

Clinical evaluation was conducted through usability engineering studies to demonstrate that intended users can safely and effectively perform critical tasks. Usability testing included both user and clinician modes, evaluation of BLE connectivity to Transcend CPAP devices, and associated cloud functionality in the intended use environment. Results confirm that the application supports safe and effective use in both home and clinical settings.

Conclusion:

Based on the results of nonclinical verification and validation testing, usability engineering evaluation, and comprehensive risk management activities, the MySleepDash Mobile Application has been demonstrated to perform as intended and to be safe and effective for its intended use. All identified risks have been mitigated to acceptable levels, and no new risks to safety or effectiveness have been identified. The testing supports that the device is substantially equivalent to the predicate device and does not raise different questions of safety and effectiveness.