July 29, 2025

Sleepiz AG
Marta Stepien
Vice-President of Clinical, Regulatory and Quality Affairs
Hornbachstrasse 23
Zurich, Zurich 8008
Switzerland

Re: K251364
Trade/Device Name: Sleepiz One+ (2.5)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II
Product Code: DRT, BZQ
Dated: July 3, 2025
Received: July 3, 2025

Dear Marta Stepien:

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,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251364

Please provide the device trade name(s).

Sleepiz One+ (2.5)

Please provide your Indications for Use below.

Sleepiz One+ is a contactless medical device intended to measure heart rate and respiration rate in adult patients, at rest or during sleep (in non-motion condition) and to detect patient presence and body movements.
The Sleepiz One+ hardware unit is intended to be used by a healthcare professional when the recordings are performed in a clinical setting, or by patients or their caregivers when the recordings are performed in a home environment. The Sleepiz One+ cloud software is intended for use by healthcare professionals.
This device is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations. It is not indicated for use on pregnant women or patients with active implantable devices.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251364

510(k) Summary

Prepared on: 2025-07-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Sleepiz AG
Applicant Address	Hornbachstrasse 23 Zurich Zurich 8008 Switzerland
Applicant Contact Telephone	+41 76 783 73 5
Applicant Contact	Ms. Marta Stepien
Applicant Contact Email	marta.stepien@sleepiz.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Sleepiz One+ (2.5)
Common Name	Vital Signs Monitoring System
Classification Name	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm & Monitor, Breathing Frequency
Regulation Number	21 CFR 870.2300
Product Code(s)	DRT, BZQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223163	Sleepiz One+	DRT

Device Description Summary

21 CFR 807.92(a)(4)

Sleepiz One+ is a contactless medical device that uses radar technology to measure respiration rate and heart rate from a resting or sleeping patient.
The Sleepiz One+ consists of a hardware unit and cloud-based software The hardware unit can be positioned on a bedside table, mounted on a stand, or attached to the wall behind the patient's bed. It is designed to monitor physiological signals by detecting small body movements, such as those caused by breathing and heartbeat, using Doppler radar. The recorded signals are then transmitted via Wi-Fi to cloud-based software, where they are analyzed to obtain respiration rate, heart rate, and body movement. These outputs can be exposed via the Application Programming Interfaces (APIs) to allow healthcare professionals the review and annotation of the data and compilation of results into reports.

Outputs
- Breathing pattern
- Instantaneous breathing rate [breaths per minute]
- Breathing rate statistics (10th, 50th, and 90th quantiles) [breaths per minute]
- Body movement
- Time in bed [hours]
- Presence detection
- Heart rate [beats per minute]
- Heart rate statistics (10th, 50th, and 90th quantiles) [beats per minute]

The overall system can be grouped into 4 major components, which are classified on the basis of the logical component interfaces where data exchange is occurring.
- Sleepiz Hardware – This is a hardware component serving as primary data acquisition device.

- Embedded Software – This encompasses the firmware running of the Sleepiz Hardware. This, together with Sleepiz hardware, is responsible for data acquisition. The embedded software forms the crux of the Sleepiz hardware such that it defines and controls the data acquisition process. The security aspects related to the operation of the device are incorporated in the design and implementation of embedded software.
- Sleep Analytics Software—The sleep analytics software is responsible for processing data from the Sleepiz Hardware and returning its analytics (e.g., breathing rate, heart rate), as well as its statistics (e.g., mean breathing rate, total recording time, etc.). This refers to the ML model deployed within the cloud software. By itself, the Sleep Analytics Software does not have an external interface. It is wholly encapsulated by the cloud software component Data Processing Layer.
- Cloud Software—The cloud software can be divided into the backend service and the analytics service. The backend service includes modules for data ingestion, a public API, a private API, and a module for sending analysis process requests. The analytics service is responsible for receiving analysis requests and interacting with the sleep analytics software.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Sleepiz One+ is a contactless medical device intended to measure heart rate and respiration rate in adult patients, at rest or during sleep (in non-motion condition) and to detect patient presence and body movements.
The Sleepiz One+ hardware unit is intended to be used by a healthcare professional when the recordings are performed in a clinical setting, or by patients or their caregivers when the recordings are performed in a home environment. The Sleepiz One+ cloud software is intended for use by healthcare professionals.
This device is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations. It is not indicated for use on pregnant women or patients with active implantable devices.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use of the subject device and the predicate device are the same; therefore, the intended use environment, intended users, including patient population, and the parameters being monitored, remain unchanged.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device like the predicate uses radar technology to collect patient's physiological signals. The collected data is then transmitted via the internet to the backend server in both devices. The subject and the predicate device differ in how physicians access patient data. While the predicate device provides a dedicated web application to log in and visualize patient data, the subject device provides Application Programming Interface (API) links enabling physicians to access patient data through third-party systems. This transition from a web-based interface to an API-based approach does not introduce new risks or compromise the safety and effectiveness of the subject device as it enhances flexibility while maintaining compliance with security and regulatory requirements. While the predicate device is battery operated, the subject device has plug-in power, but both essentially require a power source to operate. This difference raises some questions of safety and performance however those risks are well mitigated through various electrical, EMC, thermal testing.

Comprehensive verification, validation, and performance testing have rigorously assessed all differences between the devices, confirming that the subject device remains safe, reliable, and poses no new questions regarding safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical Performance Testing
As part of demonstrating substantial equivalence to the predicate device, Sleepiz AG completed a number of non-clinical performance tests. The device meets all the requirements of the overall design. Testing results confirm that the design output meets the design inputs and specifications for the device.
- Software Verification and Validation (as per IEC 62304:2006/AI:2015)
- Electrical Safety (as per IANSI AAMI ES60601-1, ANSI AAMI HA60601-1-11)
- Electromagnetic Compatibility Testing (as per IEC 60601-1-2:2014 + A1:2020)

Conclusion
Sleepiz AG considers the subject device substantially equivalent to the predicate device. This conclusion is based upon the identical intended use, principle of operation, and similar technological characteristics between the subject and predicate devices. The minor modifications made in the subject device do not alter the intended use of the device, do not impact fundamental scientific technology, or raise new questions of safety or effectiveness. The verification and validation tests performed on the subject device confirm that the device performs as intended in the specified use conditions and comparably to the predicate device. The performance testing conducted shows comparable results between the two models, thereby, demonstrating the safety and performance of the Sleepiz One+ (V.2.5). Hence, it can be concluded that the Sleepiz One+ (V.2.5) is substantially equivalent to the legally marketed predicate device.