



August 18, 2023

Sleepiz AG
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K223163

Trade/Device Name: Sleepiz One+
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, BZQ
Dated: May 7, 2023
Received: May 8, 2023

Dear Prithul Bom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Shruti N. Mistry -S
for
Jennifer Shih 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

510(k) Number (if known)

K223163

Device Name

Sleepiz One+

Indications for Use (Describe)

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).

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+ web application is intended for use by healthcare professionals.

Sleepiz One+ device can also detect the presence of patients and their body movements at rest or during sleep.

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.

Type of Use (Select one or both, as applicable)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1.1 Applicant/Submitter

Company Name : Sleepiz AG
Street Address : Hornbachstrasse 23
City : Zurich
State : Zurich
Zip Code : 8008
Phone Number : 0767837350
Fax Number : Not Applicable

1.2 Contact Person

Full Name : Marta Stepien
Phone : +41 76 783 73 50

1.3 Date of Preparation

Date of Preparation : 08/08/2023

1.4 Subject Device Information

Table - 1.1 The table below provides details on the subject device.

Trade Name	Sleepiz One+
Common or Usual Name	Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)
Classification Name	21 CFR 870.2300
Regulatory Class	2
Product Code	DRT, BZQ

1.5 Predicate Device(s)

Table - 1.2 The table below provides details on the chosen predicate device.

Predicate Type	510(k) Number	Device Name	Manufacturer	Product Code
Primary	K202464	Vital Sign Monitoring Sensor (Model :XK300)	Xandar Kardian Inc.	DRT, BZQ

1.6 Device Description

Sleepiz One+ is a contactless medical device that uses radar technology to measure respiration rate and heart rate. The device is placed on a bedside table or a stand, mounted slightly higher than the mattress level, from where it detects the presence of a patient and their physiological signals. From that position, distance changes between the device and the patient's body are captured by Doppler radar. The recorded signals are then transmitted to the cloud software where these are analyzed by the signal processing software ("Sleep Analytics Software") to obtain respiration rate, heart rate and facilitate the monitoring of the presence of the patient and their body movement. These outputs are then displayed on the web application to allow the annotation of the data, compilation of results into reports, and the management of the hardware units.

Outputs

The following parameters are estimated:

- 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]

Major Components

1. **Sleepiz One+ Hardware unit:** The Sleepiz One+ hardware unit uses radar technology that allows contactless detection of heart rate and respiration rate by sensing chest displacements originating from heartbeats and breathing activity of patients at rest or during sleep. The hardware unit can be used by a healthcare professional when the recordings are performed in a clinical setting, or by patient or their caregiver when the recordings are performed in home environment. The signals recorded by Sleepiz One+ hardware unit is then transferred via Wi-Fi to the cloud software where it is interpreted and displayed on a web application.
2. **Sleepiz One+ Web Application:** The Sleepiz One+ web application is intended to display the vital signs that have been interpreted from the derived signals by the Sleep Analytics Software on the secured Sleepiz Cloud software. The displayed data can then be accessed by a healthcare professional for retrospective analyses to remotely monitor the patient's physiological status. The intended users of the Sleepiz One+ web application are physicians and other healthcare professionals in a clinical setting. The web application allows the annotation of the data, compilation of results into reports, the management of the Sleepiz One+ hardware units and to perform other administrative functions that do not involve vital signs.

Accessories

Sleepiz hardware unit is supplied with the following components which are intended to be used in combination with it:

- Power supply
- Tablet with pre-installed application to enable data transfer via Wi-Fi and display the connectivity status Support structure to allow easy positioning of the device

Sleepiz One+ Features Summary

1. Processes the raw signals from the device and presents the data in a graphical and readable form.
2. Facilitates monitoring of patients remotely.
3. Creation of a patient on the frontend which contains patient information.
4. The ability for healthcare professionals to add annotations to the patient's graphical data.
5. Storage and display of historical patients' data.
6. The ability for healthcare professionals to manage Sleepiz hardware units remotely.
7. The ability for healthcare professionals to download the medical report in a PDF format.

1.7 Intended Use/Indications for Use

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).

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+ web application is Intended for use by healthcare professionals.

Sleepiz One+ device can also detect the presence of patients and their body movements at rest or during sleep. 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.

1.8 Comparison of Technological Characteristics with Predicate Device

The table below describes the similarities and differences between the subject device and the predicate device with regard to the intended use, principal of operation and technological characteristics.

Table - 1.3 Substantial Equivalence Discussion

Features/Technical Information	Subject Device Sleepiz One+ (K223163)	Predicate Device Vital Sign Monitoring Sensor (Model: XK300) (K202464)	Differences
Device Classification	II	II	-
Product code	DRT and BZQ	DRT and BZQ	-
Regulation number	870.2300 and 868.2375	870.2300 and 868.2375	-
Indication of use	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). 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+ web application is intended for use by healthcare professionals. Sleepiz One+ device also detects the presence of patients and their body movements at rest or during sleep. 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.	The Vital Sign Monitoring Sensor (Model XK300) is intended to measure heart rate and respiration rate in adult patients in a general care hospital environment including nursing homes. The Vital Sign Monitoring Sensor can be used for home healthcare for data collection to inform patient care but not to acutely treat a patient. XK300 monitors presence or absence of a patient in a detection area of within 7 meters. The XK300 also monitors the length of continuous patient motion or absence of patient motion.	Same
Intended user	Patients and healthcare professionals	Patients and healthcare professionals	Same
Site of use	Clinical and home environment	General Care Hospital Environment, Nursing Homes and at home	Same
OTC/Rx	Rx	Rx	Same
Patient population	Adult	Adult	Same
Accessories	Hardware unit (sensor) Tablet Support structure	Sensor, USB micro b cable	Different

Device application	Contactless	Contactless	Same
Power source	Battery operated, DC jack adapter	Wall plug-ins, USB micro b cable	Different
Data collection method	Continuous-wave radar technology	Ultra-Wide Band (UWB) radar technology	Different
Data storage	ARM Cortex-A7 Processor Chip	Arm Cortex M7 MCU chip	Different
Data transfer method	Wireless (Wi-Fi, LTE via accessory tablet)	Wireless (LTE)	Different
Data display method	Web application	Web application	Same
Data display interface	Personal computer	Personal computer	Same
Operating System	Internet browser	Internet browser	Same
Outputs	Respiration Rate (5-40 breaths/min) Heart Rate (40-120 beats/min) Presence Detection	Respiration Rate (6-55 breaths/min) Heart Rate (60-120 beats/min) Presence Detection	The parameters being measured by both the devices are the same. The difference lies in the measuring ranges covered by both the devices. See below for an explanation.

1.9 Substantial Equivalence Summary

The subject and the predicate devices have the same intended use, which is to measure patients' heart rate and respiration rate and make them available to healthcare professionals for monitoring patients remotely. Like the predicate device, the subject device is intended for healthcare professionals and adult users who can use it upon the prescription and instructions of a registered healthcare professional. The subject device is intended to be used in the same environment as the predicate device. Both devices detect the presence of patients and their movement, and additionally, the subject device also indicates breathing patterns, instantaneous breathing rate, time in bed, and breathing rate statistics by processing the obtained signals using the proprietary algorithms.

The subject device like the predicate uses radar technology to collect the signal originating from the patient. The difference lies in the fact that the subject device uses continuous-wave radar technology while the predicate uses UWB radar technology. The difference in technology does not raise any new question of effectiveness and safety because both serve the purpose of collecting raw data using radars. UWB Radars can detect the exact distance while the CW radars can measure the target velocity without ambiguity. Distance or Velocity, any of these parameters can be used to monitor the vital signs which are inferred using chest displacement. Both the devices use a Cortex processor to collect and store the received data locally. Cortex-A7 processor chips in the subject device make use of the rich operating system while Cortex-M7 MCU Chip in the predicate is based on MCUs. This difference does not raise question on the safety and effectiveness of subject device because both chips serve the intended use of collecting and storing the data locally. The collected data is then transmitted via the internet to the backend server in both devices. However, the difference lies in the fact that the predicate can work on POE, Wi-Fi, LTE-M, NB-IoT to transmit the data while the subject device transmits them via the datahub (tablet with LTE) or user's own Wi-Fi network. While the subject device is battery operated and requires to be charged every 12 hours, the predicate device has plug-in power/POE but both essentially require a power source to perform.

In the subject device, the data collection method, the data display interface, and the OS required to access the processed data/ vital sign data are the same as the predicate device. Any difference in the technological characteristics has been tested through verification and validation testing, performance testing of the device and clinical study.

1.10 Performance Data

1.10.1 Non-Clinical

Sleepiz One+ has been verified and validated using a robust and detailed verification and validation plan. The subject device has also been subjected to multiple performance tests to verify that the device characteristics meet industry standards and relevant international standards for product quality and functionality. The objective was to ensure that the subject device performs its intended functions correctly, and to confirm its quality, safety, and reliability.

The hardware-related testing verified proper assembly of the device components, battery indication functionality, HW certifications, device operations, power consumption, battery performance etc. It has also been subjected to transportation, packaging, drop and slide tests to verify the robustness of the device and its functionality under simulated conditions of the most common use case scenarios. The subject device has been subjected to electrical and mechanical safety tests as per ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) and IEC 60601-1-11 Edition 2.0 2015-01, 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, thus verifying that the subject device is electrically and mechanically safe during usage in the home and clinical-based environments.

The subject device has also passed all the emission tests performed as per IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes and Federal Register CFR 47 Part 15 subpart B:2017 Class B; and the Coexistence Immunity and Wireless Crosstalk tests performed as per 27701:2019, Security techniques — Extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management — Requirements and guidelines. and ANSI IEEE C63.27-2017, American National Standard for Evaluation of Wireless Coexistence.

To verify the operational ambient temperature, transportation, and storage ambient environmental conditions, the subject device has been tested under extreme temperature, pressure, and humidity conditions, as per clauses 4.2.2 and 4.2.3 of IEC 62366-1 Edition 1.0 2015-02, Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)] . All tests were successfully passed.

All the obtained results comply with the applicable consensus standards. The bench tests performed for the subject device addressed the parameters potentially affecting its performance and safety, and thus confirmed that the subject device is acceptable for the intended use in home and clinical-based environments.

Software

All software components have been developed as recommended by IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes. All software components have been verified against the System Requirements Specifications which was followed by system-level validation against the user needs. All tests have passed that ensures the subject device performs as intended. The performance tests of the subject device in estimating vital parameters such as the breathing rate and heart rate, toss and turn, chest displacement, and presence detection conducted on subjects at rest or in sleep were found to have passed thus evidencing the subject device's ability in meeting the acceptance criteria and thus can be considered substantially equivalent for the intended use.

Risk Analysis

Risk Analysis was performed on the subject device as recommended by ISO 14971 Third Edition 2019-12, Medical devices - Application of risk management to medical devices and risk controls were implemented to mitigate all identified hazards through suitable modifications to each components' functionality, user interfaces, labeling and packaging, IFU and User Manual.

All foreseeable cybersecurity risks associated with the subject device have been identified in addition to finding timely errors through penetration testing. This ensures the IT security of the subject device and the protection of private data (PHI and PII).

Usability

An extensive Human Factor Engineering/Usability Engineering was performed as recommended by

1. IEC 62366-1 Edition 1.0 2015-02, Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
2. Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff

to identify critical tasks and associated use errors with the medical device's use and was found to be substantially equivalent for the intended users, uses, and use environments.

1.11 Biocompatibility Testing

As Sleepiz One+ is a contactless device, this testing is not applicable for the subject device.

1.12 Clinical Testing

To evaluate the performance of the Sleepiz One+, the subject device outputs were compared to electrocardiography and pulse oximetry measurements to assess the heart rate estimation accuracy, and respiratory effort belt and nasal cannula to assess the respiration rate estimation accuracy in two clinical studies where patients were continuously monitored overnight. Polysomnography devices (Somnotouch RESP (K140861), Nox A1 (K192469)) have been used in 2 clinical studies as a comparator device, with the aforementioned subset of channels for the clinical performance assessment.

The accuracy was found to be ± 3 breaths per minute (accuracy rate 99%) and the 95% limits of agreements were -1.42 to 0.97 breaths/min compared to the respiratory effort belt; ± 5 beats per minute (accuracy rate 94%) and the 95% limits of agreements was -2.64 to 5.82 beats/min compared to ECG in 59 and 32 neurorehabilitation ward patients, respectively. Similar results were achieved in patients suspected of suffering from sleep apnea, with a slightly narrower confidence bounds of -1.3 to 0.8 breaths per minute (n=105) and 96% heart rate accuracy (n=73).

In addition, the performance of Sleepiz One+ in respiration rate estimation was evaluated against end-tidal CO₂ (etCO₂) recorded with the FDA-cleared device, manually scored by a healthcare professional. The performance of the Sleepiz One+ in estimating respiration rate was found to be ± 2 breaths/minute (accuracy 93.7%) and 95% limit of agreement was -2.51 to 2.04 breaths/minute for instantaneous breathing rate, and the average breathing rate having a mean absolute error of 0.79 breaths/minute and 95% limit of agreement of -2.63 to 2.01 breaths/minute compared to the manually scored capnography measurements from 35 participants.

Thus, the performance of Sleepiz One+ has been demonstrated on 199 subjects with wide range of age, body-mass index, gender and health conditions to reflect intended user profile. The presented results support substantial equivalence to the predicate device.

1.13 Conclusion

Sleepiz AG considers the subject device, Sleepiz One+ substantially equivalent to the predicate device. This conclusion is based upon similarities in the indication for use, principle of operation and technological characteristics. The performance and clinical data support the safety of the subject device while the verification and system validation tests results suggest that Sleepiz One+ should perform as intended in the specified use conditions and comparably to the predicate device. Thus, any technological difference between the subject and predicate devices do not pose any new questions about the safety and effectiveness for Sleepiz One+.