



August 5, 2025

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

Re: K250934

Trade/Device Name: Respiree Cardio- Respiratory Monitor System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: June 24, 2025
Received: June 24, 2025

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,


Rachana Visaria -S

Rachana Visaria, Ph.D.

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

Indications for Use

510(k) Number (if known)

K250934

Device Name

Respiree Cardio-Respiratory Monitor System

Indications for Use (Describe)

The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings and home settings.

The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.

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.

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510(k) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for Respiree Cardio-Respiratory Monitor System 510(k) premarket notification.

Sponsor: Respiree PTE Ltd.
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Date of Submission: August 4, 2025

Proprietary Name: Respiree Cardio-Respiratory Monitor System

Common Name: Breathing frequency monitor

Regulatory Class: II

Regulation: 868.2375 Breathing frequency monitor

Product Codes: BZQ

Predicate Device(s): Primary – Respiree Cardio-Respiratory Monitor K223681
Reference device – Biobeat Platform-2 K222010

Device Description: The Respiree Cardio-Respiratory Monitor System comprised of the following devices:

- Respiree Cardio-Respiratory Monitor
- Respiree Gateway and accessories (Antenna, charging cable)
- Respiree Dashboard

The Respiree Cardio-Respiratory Monitor is a wearable respiratory monitor. For measurement of respiration rate (RR), the device is affixed to the chest using a disposable adhesive patch with a hook-and-loop fastener to attach to the monitor. The device uses a vertical-cavity surface-emitting diode to emit optical light directed toward the skin. An integrated photodetector in a nearby position senses the diffused collected light. An adaptive signal processing method is used to enhance the device respiratory rate measurements by splitting the signal processing optimizations across different respiratory rate bands.

The monitor is powered by a 3.7V rechargeable, lithium-ion battery and is charged using the gateway provided. The Respiree Cardio-Respiratory Monitor transmits respiration rate raw data to the gateway via AES 256 encrypted Bluetooth wireless technology, and the latter uploads the data to the fixed secured cloud server either via Wi-Fi or LTE.

The Respiree Dashboard is a web application user interface that enable healthcare professional to access recorded respiration rate information for spot patient monitoring. The data from the Respiree Cardio- respiratory Monitor are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.

Indication for Use: The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings and home settings.

The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.

Substantial Equivalence

The subject device, Respiree Cardio- Respiratory Monitor is substantially equivalent to the primary predicate, K223681. A comparison of the key characteristics is summarized in below table.

Comparison to the Predicate Devices

	Subject Device Respiree Cardio- Respiratory Monitor System (Cardio- respiratory Monitor Model: RS001.D)	Primary Predicate Device Respiree Cardio- Respiratory Monitor (Model: RS001.2.C, RS001.2.S)	Reference Device Biobeat Platform -2	Similarities and differences
510(k) No.	K250934	K223681	K222010	-
Product Code	BZQ	BZQ	DQA, DXN, DRG, BZQ, FLL, DXG	Substantial Equivalent. All devices include the product code of BZQ.
Intended Use/Indications for Use	The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings and home settings. The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.	The Respiree Cardio-Respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings. The Respiree Cardio-Respiratory Monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.	The Biobeat Platform-2 is a wireless noninvasive remote monitoring system intended for use by healthcare professionals for spot check collection of physiological data in home and healthcare settings. This can include, functional oxygen saturation of arterial hemoglobin (%SpO ₂), pulse rate, blood pressure, respiration rate (RRp), hemodynamic parameters (stroke volume, cardiac output), and body temperature. The Biobeat Platform-2 tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO ₂ sensor, following a calibration process using an FDA-cleared oscillometric blood pressure monitor. The Biobeat Platform-2 is intended for spot-checking and tracking changes of adult patients in hospitals, clinics, long-term care,	Substantial Equivalent. All devices are indicated for spot checking of respiration rate. The primary predicate is used in hospital environments only. Reference device is used to support the home use indication.

			and at home. The data from the Biobeat Platform-2 are intended for use by healthcare professionals as an aid to diagnosis and treatment. The device is not intended for use on critical care patients.	
Measurement Principle	Uses optical sensor to measure thoracic movements.	Uses optical sensor to measure thoracic movements.	Pulse reflectance technology, four LED (red + IR) and photo diode absorbs reflected light. RRp measured by analyzing cyclic variations in the photoplethysmogram due to respiration.	Substantial Equivalent. All device uses optical technology.
Patient Interface	Sensor is adhesively attached to the patient's chest.	Sensor is adhesively attached to the patient's chest.	The device is attached to the chest skin using a biocompatible adhesive unit	Equivalent. All devices are attached to the patient's chest.
Patient Contacting Patch Material	Hypoallergenic polyurethane tape and soft silicone adhesive.	Hypoallergenic polyethylene and acrylate adhesive.	Polycarbonate, photodiode window, silicone, adhesive unit	Substantial Equivalent. All devices use biocompatible adhesive unit.
Intended Use Environment	In hospital, hospital-type facilities in non-ICU settings and home settings	In hospital, hospital-type facilities in non-ICU settings.	Hospitals, clinics, long-term care and home use	Substantial Equivalent. Both subject device and reference device are indicated for use in both hospital, hospital-type settings and home environment.
Target Population	Adult only	Adult only	Adult only	Equivalent
RX or OTC	RxOnly	RxOnly	RxOnly	Equivalent
Mode of Operation	Spot check	Spot check	Spot check	Equivalent
Parameters Monitored	Respiration rate	Respiration rate	Oxygen Saturation (SpO2) Pulse Rate (PR) Blood Pressure (BP) Respiration Rate (RRp) Body Temperature Hemodynamic	Equivalent. All devices measure respiration rate.

			parameters including: Cardiac Output (CO) Stroke Volume (SV)	
Performance Range	5 – 50 rpm	5 – 50 rpm	4 - 40 rpm	Substantial Equivalent.
Performance Accuracy (Arms)	< 3rpm	< 3rpm	+/- 3 rpm	Equivalent
Alarm	None	None	None	Equivalent
Alert	Visual and audible alert on the dashboard for - the sensor and/or gateway are offline - bad skin contact and - low battery	None	Alert for - thresholds crossing - device disconnection - bad signal - low battery	Substantial Equivalent. Although the primary predicate does not have alert function, the specific alert functions in the subject device pertain to device functionality and the differences do not raise new questions of safety and effectiveness.
Power Supply	Rechargeable Lithium-ion battery	Rechargeable Lithium-ion battery	Non- rechargeable - Lithium/ Manganese dioxide (for chest monitor) Rechargeable lithium polymer (for wrist monitor)	Substantial Equivalent. All devices use battery for the monitor.
Wireless Interface	Bluetooth LE, Wi-Fi, Cellular	Bluetooth LE	Wireless BLE, Wi-Fi/ Ethernet, Cellular	Substantial Equivalent. All devices use wireless interface for data transfer.
Dimension	44 mm x 44 mm x 13 mm	44 mm x 44 mm x 13 mm	Chest Monitor: 38 x 38 x 15 mm Wrist Monitor: 56 x 39 x 16 mm	Substantial Equivalent. All devices have small monitors that are worn on the patient's chest.
Data Storage, Transmission, Display	Respiration rate data collected from the Cardio- respiratory Monitor can be monitored and viewed from the Respiree Dashboard by the healthcare professional only.	Respiration rate collected from the Cardio- respiratory Monitor is shown on the Cardio- respiration monitor display. Retrospective data of last 12 hours can be viewed and/or downloaded from Respiree Health App.	Data from sensor is transmitted to a gateway via Bluetooth and then uploaded to the cloud via Ethernet/ Wi-Fi or Cellular. From the cloud, data is transmitted and presented in a web application for review by a healthcare professional.	Substantially equivalent. Both subject and reference devices utilize gateway to receive data from the sensor and upload them wirelessly to the server. The data is displayed on web application.

				<p>In the primary predicate device, the respiration rate is shown on the sensor's LCD screen. Retrospective respiration rate data can be viewed and/ or downloaded from the Respiree Health App.</p> <p>Difference in the method of displaying the data does not raise new questions of safety and effectiveness.</p>
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The subject device and the primary predicate (K223681) have identical intended and indications for use except that the subject device included home use environment. Specifically, the subject device uses the identical technology (i.e. same sensor units and algorithms) for measuring respiratory rate compared to the primary predicate, which is an earlier iteration of the subject device also manufactured by Respiree. Both devices affixed to the chest using a disposable adhesive patch to collect respiratory rate data.

The primary differences of the subject device as compared to the version cleared under K223681 are:

- The subject device extended the environment of use to home setting.
- Charging port is modified from micro-USB to magnetic pin.
- Cardio- respiratory monitor casing material is changed from ABS + polycarbonate to polycarbonate.
- Patch contacting material is changed to biocompatible polyurethane and soft silicon adhesive.
- The respiratory rate raw data is processed in the cloud or hospital server and is presented on web platform whereas in the predicate device, the respiration rate is read directly on the device's LCD screen, and only retrospective date can be viewed from the Respiree Health App.

The differences in the intended environment of use and the presentation of the respiration rate on web platform using the gateway are addressed by including the reference device that shares the following similarities with the subject device:

- Intended environment of use
- Utilize a gateway to receive data from the sensor and upload the data to the cloud using internet connection
- Data is processed in the cloud server
- Processed data can be accessed through the web platform for spot monitoring and viewing

Performance Data

- Software verification and validation to the Basic Software Documentation Level confirm

the device is acceptable for its intended use.

- Patient contacting components were found to be biocompatible for permanent contact duration in accordance with ISO 10993-5 and -10.
- Human factors and usability testing was conducted by intended users to support the acceptability of the human factors and usability risks associated with clinical use.
- The Respiree Cardio- respiratory Monitor System meets the electrical, EMC and wireless coexistence requirements described in IEC 60601-1, IEC 60601-1- 11, IEC 60601-1-2 and C63.27: 2021.

Conformity to Standards

Respiree Cardio-Respiratory Monitor has been tested and meets the requirements of the relevant sections of the following performance standards:

Standard	Recognition Number
ISO 10993-5 Third Edition 2009-06-01 Biological Evaluation of Medical Devices- Part 5: Test for In Vitro Cytotoxicity	2-245
ISO 10993-10 Third Edition 2010-08-01 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization	2-296
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) [Including Amendment 2 (2021)]	19-46
IEC 60601-1-11 Edition 2.1 2020-07 Consolidated version 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	19-38
IEC 60601-1-2 Edition 4.1 2020-09 Consolidated version, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36
TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	19-50
60601-1-6 Edition 3.2 2020-07 Consolidated version Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-132
IEC 62366-1 Edition 1.1 2020-06 Consolidated Version Medical devices – Part 1: Application of usability engineering to medical devices	5-129
IEC 62304 Edition 1.1 2015-06 Consolidated Version Medical device software – Software life cycle processes	13-79
IEC 62133-2 Edition 1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	19-33
UL 1642 5 th Edition Lithium Batteries	19-10

IEC 60601-4-5: 2021 Medical Electrical Equipment – Part 4-5: Guidance and Interpretation – Safety-related Technical Security Specifications	N/A
IEEE ANSI USEMCSC C63.27-2021 American National Standard for Evaluation of Wireless Coexistence	19-48

ISO 14971 Third Edition 2019 - 12 Medical devices - Application of risk management to medical devices.	5-125
ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5-134
ISTA 3A 2018 Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or less	5-126

Clinical Data

The subject device did not require new clinical studies as there is no change in the respiration rate software algorithm cleared in the previous version of the device (K223681).

Conclusion

Respiree Cardio-respiratory Monitor System has similar intended use and indications statements, technology method as the predicate devices for the measurement of respiratory rate.

Performance testing, clinical data and conformity to standards confirm that the device performs as intended. Therefore, the Respiree Cardio-respiratory Monitor System is substantially equivalent to the predicate devices.