March 11, 2021

Respiri Limited
Samaneh Sarraf
Chief Research Officer
Level 10/446 Collins Street
Melbourne, Victoria 3000
Australia

Re: K202062
Trade/Device Name: wheezo WheezeRate Detector
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic pulmonary-function interpretation calculator
Regulatory Class: Class II
Product Code: PHZ
Dated: January 29, 2021
Received: February 4, 2021

Dear Samaneh Sarraf:

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/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.

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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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)*
K202062

Device Name
wheezo WheezeRate Detector

Indications for Use *(Describe)*
wheezo is intended to detect and record abnormal breath sounds (continuous adventitious breath sounds/CABS) at the windpipe (trachea), reported as WheezeRate in adults and children (2 years and older). A licensed health care professional's advice is required to understand the meaning and importance of the wheezo readings.

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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510(k) SUMMARY

1. DATE PREPARED

Date Summary Prepared	March 10, 2021

2. 510(K) OWNER AND SUBMISSION CORRESPONDENT

Submission Sponsor	Respiri Limited
Company Address	Level 10/446 Collins Street, Melbourne, Victoria, 3000 Australia
Contact Details	Samaneh Sarraf – Chief Research Officer
	Phone: +61 491 208 783
	Email: samaneh@respiri.co

3. DEVICE IDENTIFICATION

Type of 510(k) Submission	*Traditional*
Trade or Proprietary Name	wheezo WheezeRate Detector
Common or Usual Name	wheezo
Regulation Number	21 CFR 868.1900
Regulation Description	Diagnostic pulmonary-function interpretation calculator
Product Code	PHZ
Classification of Device	II
Review Panel	Anesthesiology
Predicate Device	SonoSentry (K131285)

4. INDICATIONS FOR USE STATEMENT

wheezo is intended to detect and record abnormal breath sounds (continuous adventitious breath sounds/CABS) at the windpipe (trachea), reported as WheezeRate in adults and children (2 years and older). A licensed health care professional's advice is required to understand the meaning and importance of the wheezo readings.

5. DEVICE DESCRIPION

The Respiri wheezo WheezeRate Detector contains the following components (1) wheezo Sensing Device (2) wheezo App and (3) Secure cloud server. The wheezo transfers a user's breath sound data to the App using a Smart Device. The sound data is analysed in the algorithm, which is integrated inside the App and runs on the Smart Device.

It is a hand-held, battery-operated, computer-based, pulmonary sound detector that utilises microphones to acquire, amplify, filter, record and quantify the presence of wheezing. The breath sound is transferred using Bluetooth® technology to smartphone for detection and quantification of wheeze presence, expressed as wheeze rate.

The wheezo samples breathing and ambient sounds, and streams the audio data wirelessly via Bluetooth SPP profile to a connected Smart Device Mobile App. It does not store any recorded data into persistent memory. The Mobile App, through user interaction, must perform the standard Bluetooth pairing process to the wheezo prior to use. Wheeze rate is calculated by the Mobile App using the audio data received from the sensing device. A remote device can connect to the wheezo Sensing Device via Standard Bluetooth. The device supports Bluetooth Serial Port Protocol (SPP) mode, where asynchronous serial packets are transported using Bluetooth RFCOMM protocol. When not paired, the sensing device will be in discoverable mode.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The wheezo is an updated version of the SonoSentry (K131285)- which is the predicate device. These devices have the same indications for use, the same intended use and utilize similar technology. The specific change to the device pertains to its ability to be used with a Smartphone.

A substantial equivalence comparison of the wheezo with the SonoSentry predicate device is shown below.

Characteristics	SonoSentry (K131285)	wheezo (K202062)	Substantial Equivalence
General Device Information			
Device Name	SonoSentry	wheezo	N/A
Device Manufacturer	iSonea, Ltd.	Respiri Limited (previously called iSonea, Ltd)	N/A
Device Image			N/A
Single Use	No	No	Equivalent
Single Patient Use	Yes	Yes	Equivalent
Sterile	No	No	Equivalent
FDA regulatory Information			
Product Code	PHZ	PHZ	Equivalent
Device Class	II	II	Equivalent
Regulation No.	21 CFR 868.1900	21 CFR 868.1900	Equivalent
Clinical Equivalence			
Indications for Use	SonoSentry is intended to detect and record	wheezo is intended to detect and record abnormal breath	Equivalent

Characteristics	SonoSentry (K131285)	wheezo (K202062)	Substantial Equivalence
	abnormal breath sounds (continues adventitious breath sounds /CABS) at the windpipe (trachea), reported as WheezeRate in adults and children (2 years and older). WheezeRate™ represents the percentage of abnormal breath sound detected during the measurement time. A licensed health care professional's advice is required to understand the meaning and importance of the SonoSentry™ readings.	sound (continues adventitious breath sounds /CABS) at the windpipe (trachea), reported as WheezeRate in adults and children (2 years and older). A licensed health care professional's advice is required to understand the meaning and importance of the wheezo readings.	
Target Population	Home users: Adults, Children (2 years and older)	Home users: Adults, Children (2 years and older)	Equivalent
Anatomical Site	Trachea	Trachea	Equivalent
Intended Environment	Non-clinical (home)	Non-clinical (home)	Equivalent

Characteristics	SonoSentry (K131285)	wheezo (K202062)	Substantial Equivalence
Technological Equivalence			
Description	*The SonoSentry consists of:*	The wheezo consists of:	
	Acoustic (piezoelectric) contact sensor	Acoustic (microphone) contact sensor	Different Differences do not affect safety or performance.
	User interface LCD screen to display measurement results	Measurement displayed through the smartphone	Different Difference does not affect safety or performance. Patient receives wheeze rate via different method.
	User Interface proprietary application which allows user to record, manage and display WheezeRATE™	User Interface proprietary application which allows user to record, manage and display WheezeRATE™	Equivalent
Device Operation	User places sensor on their neck for 30 seconds to perform a passive manoeuvre. The device records, analyses the lung sounds and quantifies the presence of wheezing.	User places sensor on their neck for 30 seconds to perform a passive manoeuvre. The device records, analyses the lung sounds and quantifies the presence of wheezing.	Equivalent
Set Up	Detector is self-contained with on-board processor, recording memory and ambient microphone	Requires a smartphone. The wheezo connects via Bluetooth to the user's smartphone where processing and storage are	Different Difference does not affect safety or performance.

Characteristics	SonoSentry (K131285)	wheezo (K202062)	Substantial Equivalence
		done. Ambient microphone is on the wheezo.	
Data Transfer and Storage	From device via USB	Every recording is automatically uploaded to the cloud. However, if an Internet connection is not available, up to 20 most recent recordings will be stored locally on the smartphone.	Different The user may lose historical data if they are not connected to internet after more than 20 recordings. However, the performance and safety of the wheeze measurement is not affected.
Sensor Material	Silicone	Silicone	Equivalent
Size	130mm x 56mm x 33mm	86mm x 56mm x 50mm	Different Variation in size does not affect safety or performance.
Weight	200g (with battery) 103g (without battery)	104g (with battery)	Different Variation in weight does not affect safety or performance.
Battery	Battery powered – 2AA batteries (1.5v)	Built in rechargeable Lithium-ion polymer battery 300mAh 3.7V, 1.11Wh	Different Lithium battery complies with relevant international standards. Difference in battery does not affect safety or performance.
Graphical Interface Unit Display	On unit	On smartphone	Different The WheezeRate is available to the user. This difference does not affect the safety or performance.

7. PERFORMANCE DATA – BENCH (NON-CLINICAL)

The wheezo WheezeRate Detector passed all testing in accordance with internal company protocols, as well as international standards shown to support substantial equivalence of the subject device. This includes:

- Accuracy Testing
- Biocompatibility Testing
    - Contact Type: Surface device
    - Contact Duration: Permanent (>30 days)
- Risk Analysis including usability
- Mechanical Testing
- Electrical Safety Testing
- Electromagnetic Compatibility Testing
- Transport/Packaging Testing
- Software and Cybersecurity
    - Moderate Level of Concern

8. CLINICAL TESTING

Validation of the wheezo device output (calculated wheeze rate, 189 recordings from 56 patients and 20 healthy individuals) compared to a panel of three respiratory experts' manual calculation of the wheeze rate.

9. STANDARDS APPLIED

- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 60601-1 2005 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ISO 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 60601-1-11:2015 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
- IEC 62304:2004 Medical device software - Software life cycle processes

- IEC 62133-2:2017 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
- ISO 14971:2012 Medical devices - Applications of risk management to medical devices
- ISO 15223-1 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements

10. SUBSTANTIAL EQUIVALENCE DISCUSSION AND CONCLUSION

Both the SonoSentry and the wheezo are 1) intended to detect and record abnormal breath sounds and report it as a WheezeRate 2) used in the same environment 3) used by the same patient population and 4) used on the same site in the body, therefore there are no substantial differences between the wheezo and the predicate device.

The performance testing, including but not limited to side-by-side comparative testing demonstrated that the new device is substantially equivalent to the predicate device with respect to safety and effectiveness.

Although the two devices have different technological characteristics, evidence demonstrates that the technological characteristics of the wheezo do not raise new or different questions in relation to safety or effectiveness.

Therefore, based on the substantial equivalence analysis described above, the wheezo WheezeRate Detector, is determined to be substantially equivalent to the iSonea SonoSentry.