DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 19, 2014

iSonea, Limited
C/O Korina A. Akhondzadeh
Regulatory Consultant to iSonea
6965 El Camino Real, Suite 105-428
Carlsbad, California 92009

Re: K131285
Trade/Device Name: SonoSentry™ WheezeRate™ Detector
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic Pulmonary- Function Interpretation Calculator
Regulatory Class: II
Product Code: PHZ
Dated: July 29, 2014
Received: July 30, 2014

Dear Ms. Akhondzadeh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: **K131285**

Device Name: SonoSentry™ WheezeRate™ Detector

Indications For Use:

The SonoSentry™ WheezeRate™ Detector 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). 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.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ___ of ___

The 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information conforms to the requirements of 21 CFR § 807.92.

Manufacturer	iSonea, Ltd.
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Device Name and Classification

Trade name/Product Name	SonoSentry™ WheezeRate™ Detector
Common/Usual Name	Abnormal Breath Sound Device
Classification Name	Diagnostic pulmonary-function interpretation calculator
Classification Panel	Anesthesiology Devices
Product Code	PHZ
Regulation Number	21 CFR § 868.1900
Device Class	II

Predicate Device

Manufacturer	KarmelSonix (now known as iSonea Ltd.)
Device Name	Personal Wheezometer™
510(k) Number	K090863
Clearance Date	September 21, 2009
Indications for Use	The Personal Wheezometer™ is intended for quantifying the presence of wheezing. This device should be used under the direction of a physician or licensed healthcare professional for monitoring acoustic pulmonary functions.

Device Description

The SonoSentry™ WheezeRate™ Detector is a hand-held electronic measurement device that utilizes an acoustic contact sensor to acquire, amplify, filter, record and analyze breath sounds at the trachea for the presence of continuous adventitious breath sounds/CABS. The device calculates and outputs a WheezeRate™ based on the amount of abnormal breath sounds detected in a given time. The device is designed for use in adults and children (ages 2 years and older).

The SonoSentry™ WheezeRate™ Detector consists of:

- An acoustic contact sensor
- An air-coupled electret microphone for ambient noise rejection module
- LCD screen to display measurement results
- 4 user buttons
- Signal conditioning and digitization PCB
- Dedicated DSP
- SDRAM memory
- Embedded software

Indications for Use

The SonoSentry™ WheezeRate™ Detector 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). 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.

Substantial Equivalence

The SonoSentry™ WheezeRate™ Detector and the legally marketed predicate device, the Personal Wheezometer™ (K090863) have the same technological characteristics. The Personal Wheezometer™ is a prescription (Rx) device intended for quantifying the presence of wheezing. Wheezometer™ device is intended for use in the home and clinical settings by lay users under the direction of a physician or licensed healthcare professional for acoustically monitoring pulmonary

functions. The SonoSentry™ is available over-the-counter (OTC) as a tool to detect and record continuous adventitious breath sounds/CABS and report them as a WheezeRate ™. While the SonoSentry™ is an OTC device, a licensed healthcare professional's advice is required to understand the meaning and importance of the SonoSentry™ WheezeRate™ readings.

The technological characteristics for the SonoSentry WheezeRate™ Detector are identical to those of the predicate device. The SonoSentry™ is identical to the Personal Wheezometer™ in design, physical size, materials and function. The SonoSentry™ software is a revision of the Personal Wheezometer™ software. The revised software does not add any additional functionality for the user, and has been documented and validated in the same manner as the predicate device. There have been no other technological changes since the 510(k) clearance of the Personal Wheezometer™. The SonoSentry™ WheezeRate™ Detector is substantially equivalent to the Personal Wheezometer™.

Performance Testing - Electromagnetic Compatibility and Electrical Safety

The SonoSentry™ WheezeRate™ Detector has been tested to the following standards:

1. IEC 60601-1:1988, A1:1991, A2:1995 Medical electrical Equipment Part 1: General requirements for safety
2. IEC 60601-1-2:2001, A1:2004 Medical electrical equipment Part 1: General requirements for safety -2. Collateral standard: Electromagnetic compatibility -Requirements and tests

Performance Testing – Bench Testing

Bench testing was conducted to ensure the performance and functionality of the SonoSentry™ WheezeRate™ Detector. Testing included the following:

1. Ambient Microphone Validation Testing
2. Pressure Switch Validation Testing
3. Algorithm Validation Testing
4. Accuracy Testing
5. Sensitivity Testing
6. Embedded Performance Testing

Performance Testing – Clinical Study

A clinical study was conducted to ensure that the SonoSentry™ WheezeRate™ Detector can detect and record continuous adventitious breath sounds (CABS), including wheeze, compared to physician assessment of those same breath sounds. Sound files of pediatric and adult study subjects with a previous diagnosis of moderate to severe asthma were analyzed by the SonoSentry and an Expert Panel consisting of Board Certified Pulmonologists. The Multiple Reader/Multiple Case Study demonstrated an acceptable agreement between the output of the SonoSentry and physician detection of CABS.

Summary of Performance Testing – Conclusion

The SonoSentry™ WheezeRate™ Detector and the legally marketed predicate device have the same intended use and technological characteristics. SonoSentry™ was demonstrated to meet the requirements for electrical safety and electromagnetic compatibility as specified in the FDA recognized IEC 60601-1 and IEC 60601-1-2 standards. Bench testing involving the ambient microphone, pressure switch, algorithm, device accuracy, device sensitivity and embedded system demonstrate the performance and functionality of the device and a clinical study demonstrate that the device fulfills its intended use. The SonoSentry™ WheezeRate™ Detector is substantially equivalent to the Personal Wheezometer™, that is, SonoSentry™ is as safe and effective as the legally marketed predicate and does not raise any new types of safety or effectiveness.