K090823

SEP 21 2009

510(K) SUMMARY
WIM-PC™™

Applicant's Name: KarmelSonix
16 Palyam Avenue
Haifa 33095
ISRAEL
Tel: (972)4-861-5025
Fax: (972)4-866-7702

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837
Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***PERSONAL WHEEZOMETER™***

Classification: **Name**: Diagnostic pulmonary-function interpretation calculator
Product Code: BZM
Regulation No: 868.1900
Class: II
Panel: Anesthesiology

Device Description:

The **PERSONAL WHEEZOMETER™ ™** is a hand-held electronic measurement device that utilizes an acoustic contact sensor to acquire, amplify, filter, record and analyze pulmonary sounds from the trachea for the presence of wheezes. The device outputs a wheeze-rate score based on the amount of wheezing detected in a given time. The **PERSONAL WHEEZOMETER™** (PW) is intended to be a home use version of the PulmoTrack® (K980878) and PulmoTrack model 2010 (WIM-PC) (k071955), providing wheeze-rate information for both home and clinical settings.

The **PERSONAL WHEEZOMETER™** device 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 Statement:

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.

Predicate Device:

1. PulmoTrack model 2010 (WIM-PC), Diagnostic pulmonary-function interpretation calculator; KarmelSonix (k071955).
2. *STG Monitor Multichannel Lung Sound Analysis System* (K012387)

Performance Data:

Performance Testing – bench tests

A series of bench tests were performed to ensure that the device performs as intended. All testing results demonstrated satisfactory performance.

Performance Testing –clinical study

A clinical usability study was performed with the PERSONAL WHEEZOMETER™. The results of this usability study clearly indicate that the Personal Wheezometer is safe and effective when operated by intended users. In addition, it is easy to learn and operate the Personal Wheezometer while using the User Manual.

Tests conclusion:

We have demonstrated that the PERSONAL WHEEZOMETER™ meets its labeled performance claims, and that it is substantially equivalent to the predicate devices.

Materials:

Materials of the PERSONAL WHEEZOMETER™ device are biocompatible in accordance with ISO 10993-1.

Substantial Equivalence:

We have demonstrated that the PERSONAL WHEEZOMETER™ meets its labeled performance claims, and that it is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2009

Karmelsonix
C/O Mr. Yoram Levy
Regulatory Consultant
Qsite
31 Haavoda Street
Binyamina Israel 30500

Re: K090863
Trade/Device Name: Personal Wheezometer™
Regulation Number: 868.1900
Regulation Name: Diagnostic Pulmonary Function Interpretation Calculator
Regulatory Class: II
Product Code: BZM
Dated: August 28, 2009
Received: September 1, 2009

Dear Mr. Levy:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: **PERSONAL WHEEZOMETER™**

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.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(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)

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090863