KarmelSonix Israel Ltd

ATTACHMENT NO. 7: 510(K) SUMMARY WIM-PC™

510(K) SUMMARY
WIM-PC™

NOV - 1 2007

Applicant's Name: KarmelSonix
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Trade Name: *WIM-PC™*

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

Device Description:

The *WIM-PC™* is a computer based electronic stethoscope that utilizes two contact sensors simultaneously to acquire, amplify, filter, record and analyze pulmonary sounds from the trachea and thorax and provides high fidelity audio outputs, visual displays and printed reports.

The *WIM-PC™ system* consists of:

- Acoustic sensors (attached to the patient using adhesive pads).
- Sensor pod with a built-in dielectric microphone for ambient noise pick-up.
- Tension-sensitive respiration belt.
- A/D data acquisition device
- USB cable and signal cable

- Laptop PC unit with Data Analysis software.

Predicate Device:

PulmoTrack™ model 1010 (k980878).

Technological Characteristics

Both the *WIM-PC*™ device and its predicate device (PulmoTrack™; k980878) implement an algorithm-based set of rules to interpret acoustic pulmonary function and chest impedance measurements with respect to wheeze and respiratory pattern.

Technological Modifications from Predicate Device

The modifications between the *WIM-PC*™ and its predicate device PulmoTrack™ 1010 (K980878) are:

- Improved Acoustic sensors.
- Respiration belt (SleepSense k042253) instead of Impedance electrode
- Laptop PC instead of desk-top PC
- New version of software (Validated)
- Improved Front End Electronics
-

Indications for Use Statement:

The *WIM-PC*™ is intended for the analysis, interpretation and documentation of lung sounds.

The *WIM-PC*™ is indicated for use by or under the supervision of a physician while carrying out a provocation test, administering a bronchodilator or performing a physical examination in pulmonary function testing environment when there is a need for performing an acoustic pulmonary function measurement that quantifies the presence of wheezing. It is also indicated when there is a need to listen to amplified and filtered breath sounds.

Performance Validation:

The following tests were performed on the WIM-PC™ hardware components:

- Tension-sensitive Respiration Belt:
  - Electrical response to tension.
  - Respiratory activity detection
- Acoustic sensors: sensors frequency response and sensitivity.
- Front End performance.

The following validation tests were performed on the WIM-PC™ software:

- Wheeze detection validation test.
- Breath detection validation test.

The *WIM-PC*™ packaging was tested for its durability to shipment conditions.
The following test was performed on the WIM-PC™ packaging:

- *WIM-PC*™ packaging system integrity

Materials:

Materials of the *WIM-PC*™ system that are in contact with the human body are biocompatible in accordance with ISO 10993-1.

Substantial Equivalence:

The *WIM-PC*™ and the PulmoTrack™ model 1010 predicate device, have the same intended use and indication for use, and they are implement the same technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

KarmelSonix Israel Limited
C/O Mr. Yoram Levy
General Manager
Qsite
31 Haavoda Street
Binyamina 33095
ISRAEL

NOV - 1 2007

Re: K071955
Trade/Device Name: WIM-PC™
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic Pulmonary-Function Interpretation Calculator
Regulatory Class: II
Product Code: BZM
Dated: October 15, 2007
Received: October 18, 2007

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K071955

Device Name: *WIM-PC™*

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Prescription Use __x__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (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 Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number

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