K102229

MAR - 4 2011

510(K) SUMMARY

PulmoTrack™ 2020

510(k) Number K_____

Preparation Date: August 3, 2010

Applicant's Name: KarmelSonix Ltd
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Trade Name: ***PulmoTrack™ 2020***

Classification: **Name**: Diagnostic pulmonary-function interpretation calculator
Product Code: BZM
Regulation No: 21 CFR 868.1900
Class: II
Panel: Anesthesiology

Device Description:

The ***PulmoTrack™ 2020 is*** a computer based electronic stethoscope that utilizes an acoustic contact sensor to acquire, amplify, filter, record and analyze pulmonary sounds from the trachea and thorax and provides high fidelity audio outputs, visual displays, printed reports and automated identification of lung sounds. The data transfer may be done via Bluetooth wireless communication.

Intended Use Statement:

The ***PulmoTrack™ 2020*** is intended for the analysis, interpretation and documentation of lung sounds.
The ***PulmoTrack™ 2020*** 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.
The ***PulmoTrack™ 2020*** is indicated for patient population above two years old

Predicate Devices:

Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Clearance Date
PulmoTrack™ 2010 (WIM-PC™)	K071955	Nov 01, 2007

Performance Standards:

PulmoTrack™ 2020 complies with U.S. Federal Performance Requirements and Standards 21 CFR 801, 21 CFR 820 and FD&C act sections 501, 502, 516, 518, 519, 520.

In addition, the system complies with the following standards:

- IEC 60601-1:1998 Medical electrical Equipment Part 1: "General requirements for safety" Second addition, 1990 including amendments No.1 (1993) No.2 (1995).
- IEC 60601-1-2:2001 and IEC 60601:2005 Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.
- EN ISO 10993-1:2003 Biological Evaluation of Medical Devices.
- ISO 14971:2007 Risk management for medical devices

Technical Modifications from Predicate Device:

The ***PulmoTrack™ 2020*** is identical to the ***PulmoTrack™ 2010 (WIM-PC™)*** predicate except for the data transfer from the A/D to the PC which is done via Bluetooth wireless channel, thus contains generic software driver that handles the Bluetooth channel.

Substantial Equivalence:

The ***PulmoTrack™ 2020***:

- Incorporates the same intended use and the same technology as the ***PulmoTrack™ 2010 (WIM-PC™)***, cleared in K071955

- The Bluetooth is substantial equivalence to HOSPIRA **Vital Signs Wireless Monitoring** System, cleared in K090610

Performance Validation:

The ***PulmoTrack™ 2020*** underwent validation testing to ensure performance according to its specifications and as good as the predicate devices. All testing results demonstrated satisfactory performance.

Materials: Materials of the ***PulmoTrack™ 2020*** that are in contact with the human body are biocompatible in accordance with ISO 10993-1.

Conclusion: KarmelSonix Ltd. believes that, based on the information provided in this submission, the ***PulmoTrack™ 2020*** is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Karmelsonix
C/O Mr. Yoram Levy
Qsite
31 Haavoda St.
Binyamina, Israel 30500

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Re: K102229
Trade/Device Name: Pulmo Track™ 2020
Regulation Number: 21 CFR 868.1900
Regulation Name: Diagnostic Pulmonary-Function Interpretation Calculator
Regulatory Class: II
Product Code: BZM
Dated: January 28, 2011
Received: February 3, 2011

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. 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 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,

Anthony D. Watson, B.S., M.S., M.B.A.
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): K102229

Device Name: ***PulmoTrack™ 2020***

Indications for Use: The ***PulmoTrack™ 2020*** is intended for the analysis, interpretation and documentation of lung sounds.
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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR 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 of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number

L Schultheis

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

510(k) Number: K102229