KarmelSonix

K101022

JUL - 9 2010

510(K) SUMMARY

PulmoTrack 5050 Wholter™

Applicant's Name: KarmelSonix
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Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
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Trade Name: ***PulmoTrack 5050 Wholter™***

Submission Date: March 21, 2010

Classification:
Name: Medical magnetic tape recorder
Product Code: DSH
Regulation No: 21 CFR 870.2800
Class: II
Panel: Anesthesiology

Device Description:

The ***PulmoTrack 5050 Wholter™*** is a recording device of pulmonary sounds. The device collects the pulmonary data from 4 sensors including a sensor for ambient sounds to reduce background noise. The acquired data is filtered, undergoes A/D conversion and is stored on a flash disk. The digital data is later downloaded to a PC for analyzing using a diagnosis software package.

The ***PulmoTrack 5050 Wholter***™ device consists of:

- Acoustic sensors (attached to the patient using adhesive pads)
- Tension-sensitive respiration belt
- Ambient microphone
- A/D data acquisition device
- Firmware and Flash memory
- USB cable

Indications for Use Statement:

The ***PulmoTrack 5050 Wholter***™ is a non-invasive device intended to acquire, record and store ambulatory respiratory activity from patients for up to 24 hours. It works in concert with the PulmoTrack® Series for playback, review, analysis, editing and printing of respiratory data.

The ***PulmoTrack 5050 Wholter***™ is indicated for but not limited to recording of signals that reflect symptoms such as wheeze and cough.

Predicate Device:

1. WIM-PC (PulmoTrack 2010), Diagnostic pulmonary-function interpretation calculator; KarmelSonix (K071955).
2. Vasomedical Biox 1305; Medical Magnetic Tape Recorder, Vasomedical, Inc (K083820).

Performance Data:

Performance Testing – bench tests

The PulmoTrack 5050 Wholter underwent validation testing to ensure performance according to its specifications and that it is as good as the predicate devices. All tests demonstrated satisfactory results.

Performance Testing –clinical study

The ***PulmoTrack 5050 Wholter***™ device is used in conjunction with an analysis software package that is used by the PulmoTrack 2010 (WIM-PC) (K071955), which has been validated by performance tests for performing diagnosis of the recording.

The ***PulmoTrack 5050 Wholter***™ itself does not perform diagnosis and therefore does not require clinical testing. The safety and efficacy of the PulmoTrack 5050 Wholter™ was proven by bench performance tests.

Materials:

Materials of the ***PulmoTrack 5050 Wholter***™ device that are in contact with the human body are biocompatible in accordance with ISO 10993-1.

Substantial Equivalence:

We have demonstrated that the ***PulmoTrack 5050 Wholter***™ meets its labeled performance claims, and that it is substantially equivalent to the predicate devices.

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

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Ms. Yoram Levy
Quality Assurance/Regulatory Affairs Consultant
KarmelSonix
31 Haavoda Street
Binyamina, Israel 30500

Re: K101022
Trade/Device Name: PulmoTrack 5050 Wholter™
Regulation Number: 21CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II
Product Code: DSH
Dated: March 24, 2010
Received: April 13, 2010

Dear Ms. 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,

for

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

KarmelSonix

510(k) Number (if known): _____

Device Name: ***PulmoTrack 5050 Wholter***™

Indications for Use:

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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 OF NEEDED)

L Schultheiss

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

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