

IV. SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:

Karmel Medical Acoustic Technologies Ltd., POB 389, Tirat Hacarmel, 39554, Israel

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Name of the Device: PulmoTrack Model 1010

Predicate Devices: The PulmoTrack Model 1010 is substantially equivalent to the combination of the Littmann Brand Electronic Stethoscope and the Pulmonary Function Test Laboratory, System 1010.

Description of the Device:

The PulmoTrack is a computer based electronic stethoscope that utilizes up to five 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 1998

Dr. Charles S. Irving
Karmel Medical Acoustic Technologies Ltd.
9 Ezel Street, P.O. Box 389
Tirat Hacarmel
ISRAEL 39554

Re: K980878
PulmoTrack™ Model 1010
Regulatory Class: II (two)
Product Code: 73 BZM
Dated: October 28, 1998
Received: October 29, 1998

Dear Dr. Irving:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K980878

Device Name: PulmoTrack™ Model 1010

Indications For Use:

The PulmoTrack Model 1010 is intended for the analysis, interpretation and documentation of lung sounds.

The PulmoTrack Model 1010 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 a pulmonary function testing environment when there is a need to perform 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K980878

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____