SUMMARY OF SAFETY AND EFFECTIVENESS

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

Submitter:
Electromed, Inc.
14920 Minnetonka Ind. Rd.
Minnetonka, MN 55345
Phone# (612) 932-9387
Contact: Chet Sievert, Jr., Regulatory Consultant

Device Name:
Proprietary Name: Medpulse™ RespiratoryVest System
Common Name: Powered Percussor
Classification: Powered Percussor-Electric (21 CFR 868.5665) Class II

Predicate Device:
ThAIRapy^{R} Vest System, #K884098

Description of Device:
The Medpulse™ Respiratory Vest System is a high frequency chest wall oscillation device designed to aid in bronchial mucus clearance. The system consists of an air-pulse generator, an inflatable vest and air connection tubing. Alternating positive pressure air pulses are delivered to the inflatable vest via the air-pulse generator. Rapidly alternating positive pressure air pulses result in the inflation and deflation of the vest which provides high frequency chest wall oscillation to the patient and thus enhances clearance of mucus from the lungs. The frequency of the air-pulses, time settings and amount of pressure are operator controlled according to physician's prescription.

Intended Use:
The Intended Use of the Medpulse™ Respiratory Vest System is to provide high frequency chest wall oscillation to promote respiratory mucus clearance where external manipulations of the chest is the physician's treatment of choice.

Comparisons of Technological Characteristics:
The Medpulse™ System and the ThAIRapy^{R} System were comparitavely tested and found to be substantially equivalent with regard to form, fit and function. Both systems utilize similar technologies which deliver pulsed compressed air to the vest at similiar frequencies and pressures.

Performance Testing:
The Electromed Medpulse™ System was functionally compared and performance tested against the predicate ThAIRapy® System which resulted in a demonstration of substantial equivalence regarding pressure amplitude, pulse frequency, pressure waveform shape, and thus performance.

Conclusion:
Electromed, Inc. believes that their Medpulse™ Respiratory Vest System is substantially equivalent to the Predicate system with regard to form, fit, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

Mr. Chet Sievert, Jr.
Electromed, Inc.
14920 Minnetonko Industrial Road
Minnetonka, MN 55345

Re: K982889
Medpulse™ Respiratory Vest System
Regulatory Class: II (two)
Product Code: 73 BYI
Dated: April 29, 1999
Received: April 30, 1999

Dear Mr. Sievert:

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 (Premarket 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.

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

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

Enclosure

Device Name: Medpulse™ Respiratory Vest System

Indications for Use

The Electromed Medpulse™ RespiratoryVest System is designed specifically to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The Medpulse™ Respiratory Vest System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport.

Ruth A. Carlucci

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982889

✓ prescriptions use
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