K040367

APR - 7 2004

ELECTROMED, INC.

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New Prague, MN 56071
Phone: 952-758-9299 · Fax: 952-758-1941

February 7, 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

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

Submitter:	Chet Sievert Regulatory Affairs Electromed, Inc. 502 Sixth Avenue N.W. New Prague, MN 56071 Phone: 952.758.9299 Fax: 952.758.1941
Contact person:	Chet Sievert
Name of Device:	MedPulse® Respiratory Vest System Model 2000ez
Classification:	Powered Percussor, Class II
Predicate Device:	MedPulse® Respiratory Vest System Model 2000 510(K) number: **K982889**

Description of Device:

The proposed MedPulse® Respiratory Vest System Model 2000ez is designed to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The MedPulse® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport. The primary components of the MedPulse® System include an Air-Pulse Generator, an Inflatable Vest and Vest/Generator Connector Hose. The Air-Pulse Generator produces oscillating pressurized air-pulses that are delivered to the Inflatable Vest by the Vest/Generator Hose. The air-pulses produced by the Generator cause the Vest to rapidly inflate and deflate against the external chest wall of a patient to promote airway clearance by creating high-frequency chest wall oscillation (HFCWO) resulting in mobilization of bronchial secretions.

Intended Use:
The intended use of the Electromed MedPulse® Respiratory Vest System Model 2000ez is to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The MedPulse® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport.

Comparison of Technological Characteristics:
The proposed MedPulse® Respiratory Vest System Model 2000ez has the same technological characteristics and principles of operation as Electromed's previously cleared Medpulse® Respiratory Vest System Model 2000 (K982889). The proposed MedPulse® System will continue to use the same method of generating pressurized air-pulses as the Predicate, i.e., by dual acting pneumatic diaphragm technology. The user of the Proposed System will continue to be able to adjust air pulse frequency and pressure amplitude as the Predicate System. The Inflatable Vest and Vest/Generator Connector Hose components of the Modified MedPulse® System will remain unchanged from the Predicate System.

The reason for this submission is due to two component changes to the Air-Pulse Generator's motor. The first proposed change is to switch from a servo brush motor to a brushless motor. The motor's output performance will remain the same. A change to a brushless technology is intended to make the motor more reliable and have a longer life span. The second proposed change is to change the motor's frequency control from an analog component (i.e., potentiometer) to a digital control component. The change from analog to digital frequency control is considered to make the Air-Pulse Generator's motor more robust and reliable. The motor's digital frequency control also presents the opportunity to use the same component to control the Timer feature on the Control Panel that regulates the duration of treatment. This change allows the System to "remember' the user's previous settings for ease and more reliable use.

Performance Testing:
The proposed MedPulse® Respiratory Vest System Model 2000ez was tested and compared to the predicate Medpulse® Respiratory Vest System Model 2000 (K982889). Functional performance and electrical safety tests were performed that demonstrated no change in output performance or safety issues to result from the changes proposed.

Substantial Equivalence:
The proposed MedPulse® Respiratory Vest System Model 2000ez has the identical indications and intended use, technological characteristics and principles of operation as the Predicate device. Functional performance and electrical safety testing have demonstrated no changes in safety or effectiveness. Thus, the proposed MedPulse® Respiratory Vest System Model 2000ez is substantially equivalent to the proposed Medpulse® Respiratory Vest System Model 2000 (K982889).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2004

Mr. Chet Sievert
Regulatory Consultant
Electromed, Incorporated
502 Sixth Avenue N.W.
New Prague, MN 56071

Re: K040367
Trade Name: Medpulse Respiratory Vest System, Model 2000ez
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI
Dated: March 16, 2004
Received: March 19, 2004

Dear Mr. Sievert:

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.

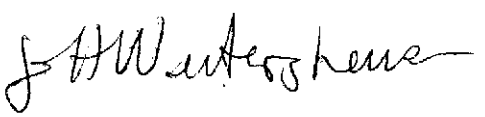
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.html.

Sincerely yours,



for 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

Indications for Use

510(k) Number: K040367

Device Name: MEDPULSE RESPIRATORY VEST SYSTEM, MODEL 2000ez

Indications For Use:

The Electromed MedPulse® Respiratory Vest System Model 2000ez is designed to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The MedPulse® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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: K040367