K051383

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Advancements in Respiratory Health.

JUN 17 2005

510(k) SUMMARY – SUMMARY OF SAFETY AND EFFECTIVENESS

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

Date of Submission:	**April 19, 2005** 17 MAY 2005
Submitter:	**Respiratory Technologies Inc., D.B.A. RespirTech**
Address:	**8095 215th Street West** **Lakeville, MN 55044**
Establishment Registration #:	**3004961434**
Owner/Operator Number:	**9068715**
Contact:	**Mario Nozzarella, CEO**
Phone:	**(952) 469-0461**
Fax:	**(952) 469-3903**
Common Name of Device:	**POWERED PERCUSSOR**
Proprietary Device Name:	**The inCourage™ System**
Classification Name:	**PERCUSSOR, POWERED-ELECTRIC**
Device Class:	**2**
Product Code:	**BYI**
Predicate Device:	**The Vest™ Airway Clearance System** **Model 104** **510(k) Number: K24309** **Product Code: BYI**

Description of Device:

The inCourage™ System is designed to assist in the loosening & eliminating of mucus from the lungs, utilizing high-frequency chest wall oscillation (HFCWO), when external manipulation of the chest is the physician's treatment of choice to increase the clearance of mucus. The primary components of The inCourage™ System include a blower, a motor-driven valve, a power supply, and a control board that are connected to an inflatable jacket through interconnecting hoses. The blower-valve combination creates oscillating air that is delivered to the jacket via the interconnecting hoses. The result is a rhythmic inflation and deflation of the jacket against the user's chest creating high-frequency chest wall oscillation, mobilization, and clearance of bronchial secretions.

Intended Use:

The inCourage™ System is indicated when external manipulation of the chest is the physician's treatment of choice to increase the clearance of mucus. It is intended for use in the treatment of a variety of Chronic Obstructive Pulmonary Diseases (COPD'S). The system promotes airway clearance and improves bronchial drainage utilizing High Frequency Chest Wall Oscillation (HFCWO).

Comparison of Technological Characteristics:

The inCourage™ System is equivalent to The Vest™ Airway Clearance System, Model 104 (K024309) in that it has the same indications for use, the same target population, the jacket and vest materials are both made of similar materials and are worn by the patient in similar fasion. The inCourage™ System utilizes ambient air regeneration, while the predicate uses reciprocating bellows. Both systems transport air pulses to the patient through interconnecting hoses. The pulses are delivered at similar rates and similar pressures. Both systems have the following features:

1. Main Unit – creates pulses of air
2. Interconnecting Hoses – delivers the air pulses from the Main Unit to the Jacket
3. Jacket – transfers the pulses of air as a percussive therapy to the patients chest area
4. Electronic User Interface – used to set and administer the therapy
5. Varying Jacket Sizes – to fit a variety of patients

The administration of therapy is essentially the same between the The inCourage™ System and the predicate device.

Performance Testing:

Functional and performance comparisons of the inCourage™ System's triangular waveform were made to the predicate device. Comparisons of the pressure, rate and volume of airflow were completed. It was concluded that the subject of this 510(k) is substantially equivalent to the predicate device.

Conclusion/Substantial Equivalence:

Respiratory Technologies Inc., D.B.A. RespirTech believes that The inCourage™ System is substantially equivalent to The Vest™ Airway Clearance System – Model 104 (K024309) 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 17 2005

Respiratory Technologies, Incorporated
C/O Mr. Robert Mosenkis
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K051383
Trade/Device Name: The InCourage™ System
Regulation Number: 868.5665
Regulation Name: Powered Percussor
Regulatory Class: BYI
Product Code: II
Dated: June 10, 2005
Received: June 13, 2005

Dear Mr. Mosenkis

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

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 (if known): K051383

Device Name: The inCourage™ System

Indications For Use:

The inCourage™ System is indicated when external manipulation of the chest is the physician's treatment of choice for increasing the clearance of mucus in patients with pulmonary disorders. The system promotes airway clearance and improves bronchial drainage utilizing High Frequency Chest Wall Oscillation (HFCWO).

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

510(k) Number: K051383

Prescription Use __X__ AND/OR (Part 21 CFR 801 Subpart D)

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)