K091557

5. 510(k) SUMMARY

JAN - 4 2010

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92(c).
Submitter	Medical Acoustics LLC
Contact Person	Name: Nicolaas J. Smit PhD, VP Science and Technology Address: 255 Great Arrow Ave., Suite 23, Buffalo, NY 14207 Phone: (905) 346-1876 Fax: (716) 853-6693 E-mail: nsmit@medicalacoustics.com
Date Prepared	May 20, 2009
Name	Lung Flute® Therapeutic
Classification Names	Incentive Spirometer
Device Classification	Classification: Class II Classification Panels: Anesthesiology Regulation Number: 868.5690
Predicate Device(s)	Acapella

Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act.
Device Description	The Lung Flute® Therapeutic is shaped like a pipe or flute with a plastic mouthpiece at one end. A Mylar reed is attached inside a square hardened plastic tube that flairs on the end to increase the internal air mass, which provides acoustical impedance. When the patient exhales through the "flute-like" device, the reed inside the tube oscillates and acts in tandem with the rest of the device and the lung cavity itself to produce a sound frequency that approximates the resonance frequency of pulmonary secretions. The Lung Flute® Therapeutic facilitates mucus clearing by generating and delivering a specific low frequency sound that vibrates the airways and lung secretions, causing lung secretions to thin and become expelled.
Indications for Use	The Lung Flute® Therapeutic is indicated for Positive Expiratory Pressure (PEP) therapy.
Technological Characteristics	The Lung Flute® Therapeutic is a hand-held, self-powered device which facilitates mucus clearing by vibrating the airways. The Lung Flute® Therapeutic uses sound to vibrate the airways and lungs at a specific frequency.
Clinical Performance	A cohort of chronic bronchitic patients underwent Positive Expiratory Pressure Therapy with the Lung Flute® Therapeutic and Acapella for eight weeks. Sputum samples were weighed, spirometry was performed and Chronic COPD questionnaire (CCQ) and St. Georges respiratory questionnaire (SGRQ) was used. A daily diary was also maintained recording breathlessness, cough and sputum scale (BCSS). Daily use of emergency inhaler was also recorded. A mixed model analysis was used to determine significance. The Lung Flute® Therapeutic and Acapella produced similar amounts of sputum, performed similarly on spirometry and questionnaires Conclusion: Positive Expiratory Pressure therapy produced similar results for both products.
Substantial Equivalence	Based on the clinical performance, the Lung Flute® Therapeutic is substantial equivalent to the Acapella; a FDA 510(k) cleared device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Dr. Nicolaas J. Smit
Vice President
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255 Great Arrow Avenue Suite 23
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JAN - 4 2010

Re: K091557
Trade/Device Name: Lung Flute® Therapeutic
Regulation Number: 21CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF
Dated: December 23, 2009
Received: December 23, 2009

Dear Dr. Smit:

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 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, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K091557

Device Name: Lung Flute® Therapeutic

Indications for Use:

The Lung Flute® Therapeutic is indicated for Positive Expiratory Pressure (PEP) Therapy.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheis

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

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