

JUN 22 2006

K060439

MEDICAL ACOUSTICS



5.0 510(k) SUMMARY

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

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Date Prepared February 10, 2006

Name *LUNG FLUTE™*

Classification Names Powered Percussor

Device Classification Classification: Class II
Classification Panels: Anesthesiology
Regulation Number: 868.5665

Predicate Device(s) Sputum induction by nebulized hypertonic saline. Pre-amendment Device

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™* 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™* 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™* is indicated for the collection of sputum samples for laboratory analysis and pathologic examination.

Technological Characteristics

The *LUNG FLUTE™* is a hand-held, self-powered device which facilitates mucus clearing by vibrating the airways. The *LUNG FLUTE™* uses sound to vibrate the airways and lungs at a specific frequency.

Clinical Performance

A cohort of chronic bronchitis patients underwent sputum induction using the *LUNG FLUTE™* and nebulized hypertonic saline. Sputum samples were analyzed for biomarkers indicative of lower respiratory tract samples. Salivary samples were analyzed representing upper respiratory tract samples. The biomarker analyzed were: Neurophil, Macrophages, Squamous Cells, Interleukin-8, Fibrinogen and Elastase. Wilcoxon signed rank test, using a $p < 0.05$, was used to compare concentrations and establish significance.

The *LUNG FLUTE™* and nebulized hypertonic saline produced similar concentrations for Neurophils, Macrophages, Squamous Cells, Interleukin-8 and were significantly different from saliva.

Conclusion: biomarkers found in sputum from samples obtained by nebulized hypertonic saline were similar to those found in sputum samples obtained using the *LUNG FLUTE™*.

Substantial Equivalence

Based on the clinical performance, the *LUNG FLUTE™* is substantial equivalent to sputum induction by nebulized hypertonic saline. A pre-amendment device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nicolaas J. Smit, PhD
VP, Science and Technology
Medical Acoustics, LLC
255 Great Arrow Avenue, Suite 23
Buffalo, New York 14207

Re: K060439
Trade/Device Name: Lung Flute®
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI
Dated: June 6, 2006
Received: June 8, 2006

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 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 (240) 276-3150 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

Appendix 1

Indications for Use

510(k) Number (if known): K060439

Device Name: Lung Flute®

Indications for Use:

The Lung Flute® is indicated for the collection of sputum samples for laboratory analysis and pathologic examination.

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)

W. Mahy for AAB

(Signature)
Chief of Anesthesiology, General Hospital,
Quality Control, Dental Devices

Device Number: K060439

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