K063645

II. 510(k) Summary

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: November 22, 2006
Submitter: **DYMEDSO, Inc.**
Address: **901A, Boul. Du Curé Boivin**
Boisbriand, Québec J7G 2S8
CANADA

Establishment Registration #: **3004365906**

Contact: **Yvon Robert, President**
Phone: **(450) 437-9601** Fax: **(450) 437-2063**

Proprietary Device Name: **Frequencer™**
Common Name of Device: **Powered Percussor**
Classification Name: **Percussor, Powered-Electric**
Device Class: **2**
Product Code: **BYI**

Predicate Devices:
K965192-Thairapy® Vest System, K972859-Flutter® D Mucus Clearance Device, K982889-Medpulse™ Respiratory Vest System, Model 1000, K012928-AbiVest™ Airway Clearance System, K972859-Flutter® D Mucus Clearance Device K031876-Electro Flo Percussor, Model 5000

Description:
The Frequencer™ provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. It induces oscillatory sound waves in the chest by means of an electro-acoustical transducer (hereafter referred to as the "Power Head") which is placed externally on the patient's chest. The Power Head is connected to a frequency generator which is capable of producing frequencies between 20 and 100 Hz. The Power Head induces sound waves in the patient's chest which are effective in loosening mucus deposits.

Intended Use:
This device is intended to be a component of postural drainage therapy by providing a convenient method of external thorax manipulation. It is indicated for patients having respiratory ailments which involve defective mucociliary clearance, as is typical in patients suffering from cystic fibrosis as well as chronic bronchitis, bronchiectasis, ciliary dyskinesia syndromes, asthma,

muscular dystrophy, neuromuscular degenerative disorders, post-operative atelectasis and thoracic wall defects.

Comparison of Technological Characteristics:
The Frequencer™ is similar to the predicate devices in terms of indications for use, contra-indications, and the intent to create vibrations in the chest wall via external stimulation. The operating principle of the proposed device differs from those of the predicate devices. Rather than mechanical percussion (Electro-Flo Percussor Model 5000), airflow-induced air pulses which are transferred through the air in the patient's throat (Flutter® D Mucus Clearance Device), or pneumatically created pressure oscillations (AbiVest™ Airway Clearance System, Medpulse™ Respiratory Vest System, Model 1000, Thairapy® Vest System), the Frequencer uses sound wave pulses from a transducer to stimulate vibration in the chest wall.

Performance Testing
Conventional chest physiotherapy (CCPT) typically involves forces externally applied to the patient's chest of 58.10 +/- 15.32 N (13.06 +/- 3.44 lb). The Frequencer™ uses much smaller forces, namely 0.4 – 3 N (0.090 – 0.674 lb). Technological data for pneumatic vests are typically expressed in units of pressure and therefore do not allow a basis for direct comparison. Frequencies for CCPT are typically 6.6 Hz, pneumatic vests (AbiVest™ Airway Clearance System, Medpulse™ Respiratory Vest System, Model 1000, Thairapy® Vest System) and the mechanical percussor (Electro-Flo Percussor Model 5000) are capable of delivering roughly 5-25 Hz. The Frequencer™ can deliver a range of frequencies from 20-100 Hz. The actual operating frequency is selected by varying until the patient feels a sympathetic resonance in the chest.

Clinical Data:
The efficacy of the Frequencer™ as compared to CCPT was assessed in a clinical trial on 20 adult patients suffering from cystic fibrosis (CF). The results show that use of the Frequencer™ results in comparable quantities of expelled sputum per session as using CCPT (9.24 ± 1.62 g for the Frequencer™ vs. 9.27 ± 1.62 g for CCPT). This is despite the fact that patients treated with the Frequencer were sitting, while those receiving CCPT were lying down, thus benefiting from postural drainage.

Conclusions:
The proposed Frequencer™ has the identical indications and intended use as well as comparable technological characteristics as the predicate devices. Only the operating principle differs, being electro-acoustic rather than pneumatic or electro-mechanical. Safety and efficacy have been demonstrated in both laboratory and clinical settings. Thus, the proposed Frequencer™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2007

Dymedso, Incorporated
C/O Ms. Jean Bigoney
Springfield Metallurgical Services, Incorporated
127 Main Street
P.O. Box 826
Springfield, Vermont 05156-0826

Re: K063645
Trade/Device Name: The Frequencer
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI
Dated: February 21, 2007
Received: February 23, 2007

Dear Ms. Bigoney:

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

INDICATIONS FOR USE

510(k) Number: K063645
Device Name: The Frequencer
Indications for Use:

The Frequencer™ provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. This device is intended to be a component of postural drainage therapy by providing a convenient method of external thorax manipulation.

It is indicated for patients having respiratory ailments which involve defective mucociliary clearance, as is typical in patients suffering from cystic fibrosis as well as chronic bronchitis, bronchiectasis, ciliary dyskinesia syndromes, asthma, muscular dystrophy, neuromuscular degenerative disorders, post-operative atelectasis and thoracic wall defects. Indications for this form of therapy are described in the Clinical Practice Guidelines for Postural Drainage Therapy of the American Association for Respiratory Care (AARC) published in 1991. This particular device provides a gentler, less painful form of therapy than the traditional "clapping" method of postural drainage therapy, allowing it to be used on patients who cannot be treated by clapping.

Prescription Use____X_____ AND/OR Over-theCounter Use_____
(Part 21 CFR 801 Subpart D) (Part 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)

[illegible]
[illegible] Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K 06 3645