

K100749

**I.510(k) Summary**

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMMA 1990 and 21 CFR Part 807.92. AUG 31 2010

Date of Submission: August 31, 2010  
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™ v2x**  
Common Name of Device: **Airway Clearance Device**  
Classification Name: **Percussor, Powered-Electric**  
Device Class: **2**  
Product Code: **BYI**

Predicate Device:  
**K063645 - Frequencer™ 1001**

Description:

The **Frequencer™ v2x** 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 65 Hz. The Power Head induces sound waves in the patient's chest which are effective in loosening mucus deposits. This model is intended for use in hospital and clinic settings only and disposable filters are available for multi-patient use.

Indications for Use:

The **Frequencer™ v2x** provides airway clearance therapy and promotes bronchial drainage by inducing vibration in the chest walls. This device is intended to be a component of chest physiotherapy by providing a convenient method of external thorax manipulation.

## Dymedso Frequencer v2x™ Powered Percussor

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.

The Frequencer™ v2x is only intended for use in hospitals and clinics.

### Comparison of Technological Characteristics:

The **Frequencer™ v2x** is identical to the predicate device in terms of indications for use, contra-indications, acoustic operating principle and basic electronics. The polymer material used for the housing and adapters has been changed from a polyurethane to a polycarbonate/ABS blend. In addition, the user interface no longer consists of touch pad buttons and an LCD display but is now a touch screen. The device is only intended for use in hospitals or clinics as opposed to the predicate, which was intended for home or residential environments.

### Performance Testing

The device was tested in accordance with IEC 60601-1 for electrical safety and tested in accordance with IEC 60601-1-2 for electromagnetic radiation, with acceptance criteria consistent with a Type A device for non-domestic environments such as hospitals or clinics. Software verification and validation testing has also been performed on the device.

Performance bench testing was conducted to determine the maximum force applied by the device in comparison to the predicate device. The testing demonstrated a similar, though slightly lower maximum applied force in comparison to the predicate. Both devices still provide considerably lower forces than applied during Conventional Chest Physiotherapy (CCPT). The lower forces produced by the Frequencer™ may be able to provide a gentler treatment compared to CCPT. Clinical testing conducted on the original Frequencer™ have demonstrated comparable sputum weights produced after treatment with the Frequencer™ in comparison to Conventional Chest Physiotherapy (CCPT) in subjects with Cystic Fibrosis (CF). In vitro flow rate measurements of mucus through a capillary tube also demonstrated higher flow rates of mucus when using the Frequencer compared to no treatment.

*Dymedso* Frequencer v2x™ Powered Percussor

Conclusions:

The proposed **Frequencer™ v2x** has the identical indications, operating principle and electronics as the predicate device **Frequencer™ 1001**. The only differences are the polymer housing material, user interface, and intended environments. In addition, disposable filters are available for use in multi-patient settings. The performance testing provides validation of new features of this device and demonstrates similar performance characteristics to the predicate device. Thus, the proposed **Frequencer™ v2x** is substantially equivalent to the predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

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

AUG 31 2010

Re: K100749  
Trade/Device Name: Frenquencer™ v2x  
Regulation Number: 21 CFR 868.5665  
Regulation Name: Powered Percussor  
Regulatory Class: II  
Product Code: BYI  
Dated: August 2, 2010  
Received: August 5, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,



Anthony D. Watson, B.S., M.S., M.B.A.  
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**

K100749

510(k) Number (if known):

Device Name: **Frequencer™ v2x**

**Indications for Use:**

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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.

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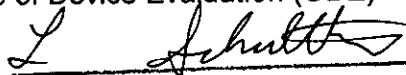
Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use \_\_\_\_\_  
(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)



(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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