K133057

510(k) Summary

MAY 2 3 2014

Date Prepared	23-May-14
Company	Westmed, Inc. 5580 South Nogales Highway Tucson, AZ 85706 Tel – 520-294-7987 Fax – 520-294-2780
Official Contact:	John McKinnon - CEO
Proprietary or Trade Name:	Vibralung Acoustical Percussor
Common/Usual Name:	Electric powered percussor
Classification / CFR:	BYI / CFR 868.5665 / Class 2
Device:	Vibralung Acoustical Percussor
Predicate Devices:	Dymedso - Frequencer – K063645 and K103176 (Primary) DHD Healthcare (Smiths) – Acapella – K991561 and K002768 Medical Acoustics – Lung Flute – K091557

Device Description: The proposed Vibralung Acoustical Percussor provides airway clearance therapy (ACT) and promotes mucokinesis by inducing vibration in airways by vibrating the column of gas in the airways at a variety of different frequencies. It is an acoustic device that induces oscillatory sound waves by means of an electro-acoustical transducer (audio speaker), referred to as the "Hand-held Transducer" or HHT, which is interfaced to the patient's airway through a mouthpiece. The transducer unit is connected to a frequency generator, referred to as the "Treatment Control Unit" or TCU, which is set to produce frequencies between 5 and 1,200 Hz in different ranges that are user-selectable.

The HHT directs sound waves into the patient's airways through a waveguide and a mouthpiece.

In addition, the Vibralung can provide Positive Expiratory Pressure (PEP) and may simultaneously provide nebulized aerosol drug delivery.

There are two different Y-adapters available that act as "waveguides" to direct sound waves from the audio speaker in the HHT to the mouthpiece that is held in the patient's mouth in the same manner as with other breathing treatment mouthpieces.

The purpose of the Y-adapters is two-fold:

- To direct the sound waves into the airway opening, and
- To provide separate pathways for inhalation and exhalation gas flow with minimal mixing and rebreathing of exhaled gas.

The Standard Y-adapter allows ambient breathing without aerosol therapy. It contains an ambient air intake port with a valve for one-way inspiratory flow while preventing exhalation through the port. The exhalation is directed through one branch of the Y-adapter and out to the room through a variable expiratory resistor that also provides Positive Expiratory Pressure (PEP).

The other Y-adapter (Aerosol Y-adapter) allows the device to be coupled to the airway opening (mouth) while interfaced with Westmed's Circulaire aerosol drug delivery system to enable aerosolized medication to be delivered concomitantly with ACT. In this configuration, inhalation and exhalation pathways plus PEP are incorporated into the Circulaire device.

Indications for Use:
The Vibralung Acoustical Percussor is indicated as an airway secretion clearance device that creates vibrations in the airways and as a lung expansion device that applies Positive Expiratory Pressure (PEP) as a patient breathes through the device. It may be used to promote bronchial drainage, airway clearance and expectoration. The Vibralung may be used simultaneously with aerosol drug delivery.

Patient Population - Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems, patients with neuromuscular disease affecting the ability to effectively cough. Anyone who is able to read and / or follow verbal instructions

Environment of Use – Hospital and Home

Contraindications: ACT or use of the Vibralung Acoustical Percussor, especially with Positive Expiratory Pressure, may be contraindicated in patients who have untreated air leaks, tension pneumothorax, bronchopleural fistula, recent hemoptysis, or pulmonary hemorrhage because it may exacerbate those conditions. Prescribers should weigh benefits against risks in patients with these conditions.

Adverse Reactions: If the patient complains of dry or sore throat or mouth brought about by treatment with the Vibralung, consider adding nebulization with normal saline if it is not already being done. If the patient complains of sore mouth, jaw or teeth brought about by using the Vibralung device, the healthcare practitioners should assess the patient. If the patient complains of dizziness or light-headedness, assess the patient for possible hyperventilation while using the device. If the patient appears to be hyperventilating, pause the treatment and coach the patient to alter their breathing pattern appropriately. Any other adverse reactions should be fully assessed before continuing therapy with the Vibralung Acoustical Percussor.

Level of Patient Contact and Duration:

In accordance with G95-1 and ISO 10993-1 the Vibralung components are primarily considered as:

Components in the nebulized aerosol gas pathway

- External Communicating (indirect contact but in the gas pathway)
- Tissue Contacting
- Permanent Duration of Use for those components in the nebulizer aerosol path

Components in the gas pathway but NOT in the nebulized aerosol gas pathway

- External Communicating (indirect contact but in the gas pathway)
- Tissue Contacting
- Limited Duration of Use (less than 24 hr of accumulated exposure)

Components in Direct Contact patient contact

- Surface Contacting
- Mucosal membrane
- Limited duration of use (less than 24h)

All the materials in the Vibralung have been utilized in Westmed devices which have substantially equivalent levels of patient contact and duration of use.

Predicate Device Comparison:

Table 1: Predicates by Indications for Use and Airway Clearance technology

Predicate	Airway Clearance	PEP	Aerosol delivery	Contact with airway	Applied During	Technology
Frequencer K063645 K100749 K103176	X	-	-	External Chest wall	Inhalation / exhalation	Acoustical power head applied to chest wall
Acapella K991561 K002768	X	X	X	Direct Mouthpiece	Exhalation	Interrupted airflow at a frequency
Lung Flute K091557	X	X	-	Direct Mouthpiece	Exhalation	Interrupted airflow with reed for frequency

Table 2 - Substantial Equivalence Table - Frequencer

Criteria	Vibralung	Dymedso Frequencer K063645, K100749, K103176
FDA Classification	BYI – Percussor, power-electric 868.5665	BYI – Percussor, power-electric 868.5665
Indications for Use	The Vibralung Acoustical Percussor is indicated as an airway secretion clearance device that creates vibrations in the airways and as a lung expansion device that applies Positive Expiratory Pressure (PEP) as a patient breathes through the device. It may be used to promote bronchial drainage, airway clearance and expectoration. The Vibralung may be used simultaneously with acrosol drug delivery.	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.
Other indications	Applies Positive Expiratory Pressure (PEP) Simultaneously used with nebulizer	No
Environments of use	Hospital and home settings	Hospital and home settings
Patient Population	Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems, patients with neuromuscular disease affecting the ability to effectively cough. Anyone who is able to read and / or follow verbal instructions.	Patients having respiratory ailments which involves defective mucociliary clearance, as is typical in patients suffering from Cystic Fibrosis, chronic bronchitis, bronchiectasis, ciliary dyskinesia syndrome, asthma, muscular dystrophy, neuromuscular degenerative disorders, post-operative atelectasis and thoracic wall defects.
Prescription/OTC	Prescription use	Prescription use
Principle of Operation	Acoustical generator uses sound waves to vibrate the gas column in the airway at various frequencies	Acoustical generator applied externally to the chest that transmits sound through the chest wall, vibrating the airways.
Technology employed	Loudspeaker controlled to apply a range of frequencies	Loudspeaker controlled to apply a range of frequencies
How it interfaces with the patient	The patient uses a mouthpiece and the acoustical sound is directed to the airway	In contact with the chest wall, but the vibrations of the loudspeaker create a vibration and frequency through the chest wall to the airways
Patient Effort	Effort independent	Effort independent
Patient Breathing Maneuver	Normal inspiratory & expiatory pattern	Normal inspiratory & expiatory pattern
Chest wall Frequency	N/A	20 – 100 Hz
Airway Acoustical Frequency	5 – 1,200 Hz generated; up to 7,000 Hz actual resulting from harmonics and resonance	20 – 65 Hz generated and applied to external chest wall; up to 9,000 Hz actual resulting from harmonics and resonance

The Vibralung is viewed as substantially equivalent to the predicate, Dymedso The Frequencer, K063645, K100749, and K103176, because:

Indications
The airway clearance and bronchial drainage indications for use are substantially equivalent.
Discussion - The indications for use are substantially equivalent for the proposed device and the predicate, Dymedso Frequencer, K063645, K100749, and K103176.

Technology
The Vibralung technology of creating a frequency for vibrating the airways is substantially equivalent to the predicate Dymedso Frequencer, K063645, K100749, and K103176. They both use a loudspeaker that can generate acoustical sound at various frequencies that vibrate the gas in the airways.
Discussion - The technology is substantially equivalent for the proposed device and the predicate, Dymedso Frequencer, K063645, K100749, and K103176.

Environment of Use
The environments of use, hospital and home are substantially equivalent to the predicate.
Discussion - The environments of use are substantially equivalent to the predicate, Dymedso The Frequencer, K063645, K100749, and K103176.

Patient Population
The patient population of those with Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems is substantially equivalent to the predicate.
Discussion - The patient population for which airway clearance is indicated, is substantially equivalent to the predicate.

Table 3 – Substantial Equivalence Table – Acapella

Criteria	Vibralung	DHD - Acapella K991561 K002768
FDA Classification	BYI – Percussor, power-electric 868.5665	BWF – Incentive Spirometer 868.5690
Indications for Use	The Vibralung Acoustical Percussor is indicated as an airway secretion clearance device that creates vibrations in the airways and as a lung expansion device that applies Positive Expiratory Pressure (PEP) as a patient breathes through the device. It may be used to promote bronchial drainage, airway clearance and expectoration. The Vibralung may be used simultaneously with aerosol drug delivery.	Indicated for use as a PEP device. Improves clearance of secretions, reduce the need of postural drainage, facilitates opening of airways, prevents or reverses atelectasis. It may be used simultaneously with nebulized aerosol drug delivery.

Criteria	Vibralung	DHD - Acapella K991561 K002768
Environments of use	Hospital and home settings	Hospital and home settings
Patient Population	Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems, patients with neuromuscular disease affecting the ability to effectively cough. Anyone who is able to read and / or follow verbal instructions.	Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems Patients with atelectasis.
Prescription/OTC	Prescription use	Prescription use
Principle of Operation Secretion Clearance	Acoustical generator uses sound waves to vibrate the "column" of gas in the airways at various frequencies	Creates airflow interruption during exhalation which vibrates the "column" of gas in the airways at various frequencies
Technology employed for Secretion Clearance	Loudspeaker controlled to apply a range of frequencies	Unstable counterweighted lever and magnet mechanism action during exhalation, to interrupt the exhaled airflow as it is directed through the device. This deliberately unstable mechanism repeatedly interrupts airflow, affecting both frequency and amplitude. Backpressure (PEP) is simultaneously created by directing airflow through an adjustable small diameter restriction.
Technology employed for Positive Expiratory Pressure (PEP)	Variable resistor valve is placed in the expiratory part of the wye; generates PEP up to 4 cmH_2O during resting breathing or 10 – 20 cmH_2O during PEP maneuver.	Airflow is diverted through a restriction in the device creating a backpressure which is PEP up to 60 cmH_2O at 30 L/min
Principle of Operation PEP	Creating resistance to exhalation creates backpressure known as PEP which opens the airways	Creating resistance to exhalation creates backpressure known as PEP which opens the airways
Technology employed for in-line nebulizer	Y-adapter that allows for a nebulizer to be placed in-line	Connector that allows for a nebulizer to be placed in-line
Principle of Operation Nebulizer	Standard off-the-shelf nebulizer that is fitted in-line and has a reservoir, spacer like device. Circulaire II (K955047 / K926055)	Standard off-the-shelf nebulizer that is fitted in-line
How it interfaces with the patient?	The patient uses a mouthpiece	The patient uses a mouthpiece
Patient Effort	Effort independent	Effort dependent
Patient Breathing Maneuver	Normal inspiratory & expiratory pattern	Deliberate exhalation maneuver
Airway Acoustical Frequency	5 – 1,200 Hz generated; up to 7,000 Hz actual resulting from harmonics and resonance	~11 Hz up to >10,000 Hz actual resulting from harmonics and resonance

The Vibralung is viewed as substantially equivalent to the predicate DHD – Acapella – K991561 and K002768 because:

Indications: There are 3 indications for use for comparing the Vibralung to the DHD – Acapella.

- The airway clearance and bronchial drainage indications for use are substantially equivalent.
- Indicated for use as a PEP device which facilitates opening of airways is substantially equivalent.
- It may be used simultaneously with aerosol drug delivery.

Discussion - The indications for use are substantially equivalent for the proposed device and the predicate, Dymedso Frequencer, K063645, K100749, and K103176.

Technology

Secretion Clearance: The Vibralung technology of creating a frequency for vibrating the airways is different than the predicate DHD – Acapella, K991561 and K002768. Vibralung uses a loudspeaker to generate sound waves that create acoustical vibrations in the airways. The predicate, DHD – Acapella, uses an unstable counterweighted balance mechanism that varies the frequency and amplitude of a pressure wave and creates vibration in the airway during exhalation. Nevertheless, the physiological effects are the same regardless of the mechanism that produces the vibrations.
Discussion - The technology for creating the vibrations in the airway is done differently but the results are the same. The physiological results are substantially equivalent to the predicate DHD – Acapella – K991561 and K002768.

Positive Expiratory Pressure (PEP): Both the Vibralung and predicate, DHD Acapella, K991561 and K002768, create expiratory resistance / pressure during exhalation. The Vibralung does it with an adjustable resistor valve in the exhalation side of the Y-adapter and the predicate has a diverting air flow path that creates backpressure (resistance) during exhalation.
Discussion - Both devices create PEP during exhalation.

Simultaneous nebulized aerosol drug delivery: Both the Vibralung and predicate DHD – Acapella, K991561 and K002768 can accommodate an in-line nebulizer should the clinician wish to provide aerosol treatment while a patient is using the devices.
Discussion – The use of an in-line nebulizer is substantially equivalent - both devices allow for an in-line nebulizer to be attached.

Environment of Use: The environments of use, hospital and home, are substantially equivalent to the predicate.
Discussion - The environments of use are substantially equivalent to the predicate DHD – Acapella, K991561 and K002768.

Patient Population: The patient population of those with Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems is substantially equivalent to the predicate.
Discussion - The patient population is substantially equivalent to the predicate DHD – Acapella, K991561 and K002768.

Table 4 – Substantial Equivalence Table – Lung Flute

Criteria	Vibralung	Medical Acoustics Lung Flute K091557
FDA Classification	BYI – Percussor, powered-electric 868.5665	BWF – Incentive Spirometer 868.5690
Indications for Use	The Vibralung Acoustical Percussor is indicated as an airway secretion clearance device that creates vibrations in the airways and as a lung expansion device that applies Positive Expiratory Pressure (PEP) as a patient breathes through the device. It may be used to promote bronchial drainage, airway clearance and expectoration. The Vibralung may be used simultaneously with aerosol drug delivery.	Mentioned in 510(k) summary – facilitates mucus clearing by vibrating the airway. The Lung Flute is indicated for PEP therapy.
Environments of use	Hospital and home settings	Hospital and home settings
Patient Population	Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems, patients with neuromuscular disease affecting the ability to effectively cough. Anyone who is able to read and / or follow verbal instructions.	Not specific but mentions COPD patients
Prescription/OTC	Prescription use	Prescription use
Principle of Operation Secretion Clearance	Acoustical generator uses sound waves to vibrate the "column" of gas in the airways at various frequencies	Uses acoustical impedance to produce sound waves that vibrate the "column" of gas in the airways at various frequencies
Technology employed for Secretion Clearance	Loudspeaker controlled to apply a range of frequencies	Reed which vibrates during exhalation to produce sound frequencies
Technology employed for Positive Expiratory Pressure (PEP)	Variable resistor valve is placed in the expiratory part of the wye; generates PEP up to 4 cmH_2O during resting breathing or 10 – 20 cmH_2O during PEP maneuver.	Airflow encounters restriction through the device creating a back pressure which is PEP 2.5 cm H_2O.
Principle of Operation PEP	Creating resistance to exhalation creates backpressure known as PEP which opens the airways	Creating resistance to exhalation creates backpressure known as PEP which opens the airways
How it interfaces with the patient?	The patient uses a mouthpiece	The patient uses a mouthpiece
Patient Effort	Effort independent	Effort dependent
Patient Breathing Maneuver	Normal inspiratory & expiratory breathing pattern	Deliberate exhalation maneuver
Airway Acoustical Frequency	5 – 1,200 Hz generated; up to 7,000 Hz actual resulting from harmonics and resonance	~11 Hz up to >10,000 Hz actual resulting from harmonics and resonance

The Vibralung is viewed as substantially equivalent to the predicate Medical Acoustics – Lung Flute – K091557 because:

Indications: There are 2 indications for use for comparing the Vibralung to the Medical Acoustics – Lung Flute.

- The airway clearance and bronchial drainage indications for use are substantially equivalent.
- Indicated for use as a PEP device that facilitates opening of airways is substantially equivalent.

Discussion - The indications for use are substantially equivalent the proposed Vibralung and to the predicate Medical Acoustics – Lung Flute – K091557.

Technology

Secretion Clearance: The Vibralung technology for creating a frequency for vibrating the airways is different than the predicate Medical Acoustics – Lung Flute – K091557. Vibralung uses a loudspeaker to generate sound waves that create acoustical vibrations in the airways, while the predicate, Medical Acoustics – Lung Flute uses a vibrating reed that provides a sound frequency that creates vibration in the airway during exhalation.

Discussion – The technology for creating the vibrations in the airway is done differently but the results are the same. The physiological results are substantially equivalent to the predicate Medical Acoustics – Lung Flute – K091557.

Positive Expiratory Pressure (PEP): Both the Vibralung and predicate Medical Acoustics – Lung Flute – K091557 create expiratory resistance / pressure during exhalation. The Vibralung does it with an adjustable resistor valve in the exhalation side of the Y-adapter and the predicate has a diverting air flow path that creates some backpressure (resistance) during exhalation.

Discussion - Both devices created PEP during exhalation. Both devices produce about a substantially equivalent level of expiratory resistance (PEP), 4 cm H_2O for Vibralung and 2.5 cm H_2O for the Lung Flute.

Environment of Use: The environments of use - hospital and home are substantially equivalent to the predicate.

Discussion – The environments of use are substantially equivalent to the predicate Medical Acoustics – Lung Flute – K091557.

Patient Population: The patient population is not specifically listed in the predicates Indications for Use or 510(k) Summary. However, there are references to patients who require secretion clearance as well as PEP treatment, thus the patients would, by implication, include those with Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems as substantially equivalent to the predicate.

Discussion – The patient population is substantially equivalent to the predicate Medical Acoustics – Lung Flute – K091557.

Non-clinical Testing Summary :

We performed a number of non-clinical tests to demonstrate that the Vibralung Acoustical Percussor to be substantially equivalent and will perform within specification.

- Verification and Validation Testing
- Inspiratory Resistance
  - Inspiratory Resistance
  - Airway Pressure and Sound Pressure Level
- Mechanical Dead Space
- Aerosol Performance During Treatment
  - Particle Characterization with and without aerosolization
  - Particle Characterization of the Acapella Predicate with and without aerosolization
  - Acoustic – Aerosol Performance
- Comparative Acoustical Testing vs. Predicates
- Treatment Control Unit
- Human Factors Study
- Accelerated Aging
- Cleaning
- Electrical Safety, EMC, EMI
  - IEC 60601
  - EN 5501
  - IEC 60601-1 236815
  - IEC 60601-1-11 236815-1
  - IEC 62133

Comparison of Predicate Devices:

We have performed comparative testing for the Vibralung and the Predicates. The spectral analysis patterns for the Vibralung are different than the predicate devices for a number of reasons, but they also contain the same frequencies.

- The Vibralung lung device generates sound frequencies in the range of 5 to 1,200 Hz. However, when these frequencies are reproduced by the loudspeaker, mounted in the HHT and conducted to the patient through a waveguide Y-adapter, the sound experiences the normal phenomena of harmonics and resonance with the following ranges:

Low Mode	5 Hz to ~1,700 Hz
Medium Mode	5 Hz to 3,000 Hz
High Mode	5 Hz to 3,000 Hz
Random Noise Mode	5 Hz to >7,000 Hz

- Likewise, the predicate devices generate sound frequencies as a consequence of their operation. These frequencies likewise experience harmonics and resonance that yields resulting frequencies closely substantially equivalent to the Vibralung:

Blue Acapella	<11 Hz to >10,000 Hz
Green Acapella	<11 Hz to >10,000 Hz
Lung Flute	<11 Hz to >10,000 Hz
The Frequencer	30 Hz to ~9,000 Hz (@ 65 Hz setting)

- Like the predicate devices, the Vibralung has a number of frequency components. But unlike the predicates, many of these are deliberately created.
- Like the predicate devices, the Vibralung is also subject to resonance whereby additional frequencies are created due to internal resonance and harmonics.
- Like the predicate devices, the Vibralung demonstrates low frequency components. Unlike the predicate devices, they are not as defined and pronounced.

Summary: These studies demonstrate that all the predicate devices demonstrate acoustic frequencies that are inclusive of, and even higher than, those frequencies generated by the Vibralung Acoustical Percussor.

Both the predicate devices and the Vibralung generate resonance and harmonic frequencies. This is a normally occurring phenomenon any time sound is directed through tubes.

The Vibralung and the predicate devices are substantially equivalent in terms of the acoustic frequencies and amplitudes they employ for airway clearance therapy.

Clinical Testing:

Two (2) studies were performed with the Vibralung Acoustical Percussor.

Study 1 included 10 subjects to determine if Vibralung can be a positive treatment option to improve mucous discharge in subjects with cystic fibrosis (CF); and to assess if the treatment was safe for the patient. The subjects with mild to moderate CF were subjected to two treatments: (1) with sound, and (2) without sound, each for a period of 20 minutes on two different days. On each visit we measured pulmonary function, lung clearance index (LCI), symptoms and peripheral oxygen saturation (SaO2) at baseline and 1 and 4 hours post-treatment, and total sputum production was collected over 4 hours. Although the results indicated no change from baseline to 4 hours post treatment in FVC, FEV1, and SaO_2, there was a greater improvement to LCI with the device use with sound than without sound. The results demonstrated that the Vibralung device is safe for patient use.

Study 2 was designed to assess the effects of the Vibralung on sputum clearance when compared to the Vest predicate for five days. There were 11 subjects. Similar results in sputum wet weight, pellet weight, or dry weight, when comparing the 2 devices. The results demonstrated that the Vibralung is equivalent in performance for sputum clearance.

Substantial Equivalence Conclusion:

The sponsor has demonstrated through performance testing, design and features, non-clinical, and clinical testing that the proposed Vibralung Acoustic Percussor device does not raise any new safety concerns and is substantially equivalent to the identified predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 27, 2014

Westmed, Inc.
C/O Mr. Paul Dryden
President,
Promedic, Inc.
5580 S. Nogales Hwy.
Tucson, AZ 85706 USA

Re: K133057
Trade/Device Name: Vibralung Acoustic Processor
Regulation Number: 21 CFR 868.5665
Regulation Name: Electric powered percussor
Regulatory Class: Class II
Product Code: BYI
Dated: April 24th, 2014
Received: April 25th, 2014

Dear Mr. Dryden,

This letter corrects our substantially equivalent letter of May 23, 2014.

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 contact 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133057

Device Name
Vibralung Acoustical Percussor

Indications for Use *(Describe)*

The Vibralung Acoustical Percussor is indicated as an airway secretion clearance device that creates vibrations in the airways and as a lung expansion device that applies Positive Expiratory Pressure (PEP) as a patient breathes through the device. It may be used to promote bronchial drainage, airway clearance and expectoration. The Vibralung may be used simultaneously with aerosol drug delivery.

Patient Population - Cystic Fibrosis, COPD, asthma and lung diseases with secretory problems, patients with neuromuscular disease affecting the ability to effectively cough. Anyone who is able to read and / or follow verbal instructions

Environment of Use – Hospital and Home

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Anya C. Harry -S
2014.05.23 03:23:19 -04'00'

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