MAR 2 8 2014

510(k) Summary, Section 807.92(a)(2)

K132988

Submitted by	Lung Assist, Inc. 4655 Kirkwood Court Boulder, CO 80301

Contact Person	Lewis Ward Vice President Operations 4655 Kirkwood Court Boulder, CO 80301 303-516-1024 303-530-4774 Fax lwward@qwest.net

Date Prepared	March 26, 2014

Product Name	Trade Name: Vital Cough Common Name: Cough Assist Device

Classification	Noncontinuous Ventilator 868.5905, Product Code NHJ Class II, Anesthesiology Panel

Intended Use	The Vital Cough is intended for use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in a hospital, institutional setting, or home use given adequate training. For use on adult or pediatric patients.

Technological Characteristics	The device is an electromechanical software controlled device housed in a metal and polymer case. A touch screen displays outputs and receives commands from the user. The device develops positive and negative pressure through an adjustable blower. In inhale mode the lungs are inflated. The device rapidly shifts to providing negative pressure with the intended goal of rapidly deflating the lungs to stimulate an effective patient cough. A flutter feature developed by an oscillator butterfly valve may be activated during exhalation to assist in loosening and removing secretions.

Non-clinical Testing	The Vital Cough complies with the IEC 60601-1 general requirements for electrical safety and IEC 60601-1-2 electromagnetic compatibility standards. No toxic substances have been found in the output air of the device. The device conforms to ISO 9703 anesthesia and respiratory care alarm signals, auditory and visual. Characterization by pressure and flow of the Acapella predicate and the Vital Cough with flutter feature is included in this submission.

Substantial Equivalence	The Vital Cough with flutter feature is substantially equivalent to the Vital Cough without a flutter feature (K120277) and the Acapella flutter device (K002768) based on comparative testing, compared specifications, waveform characterization and analysis, and indications for use.

Key Feature Comparison, MI/E Device

Feature	Vital Cough with Flutter	Vital Cough K120277 (predicate device)	Acapella K002768 (predicate device)
Maximum Pressures	+/- 50 cm H_2O	+/- 50 cm H_2O	Human effort 19 cm H_2O
Maximum Exhalation Peak Flow	269 LPM	420 LPM	71 LPM
Flutter Frequency	0-20 Hz	No flutter	0-19 Hz
Flutter Waveform Technology	Square waveform	No flutter	Square waveform
Benefits	• Creates a negative expiratory pressure, a positive inspiratory pressure, and vibrations. • Improves secretion clearance. • Adjustable frequency and pressure. • Accommodates patients with very low flow rates. • Creates a positive inspiratory pressure	• Creates a negative expiratory pressure and a positive inspiratory pressure. • Improves secretion clearance. • Adjustable pressure. • Accommodates patients with very low flow rates. • Creates a positive inspiratory pressure	• Creates a positive expiratory pressure (PEP) and vibration therapy. • Improves secretion clearance. • Inhalation without removing device from the patient's mouth. • The device performs in any spatial orientation. • Allows patients to adjust frequency and pressure. • Accommodates patients with very low flow rates. • No effect on inspiration.

Mode of Operation	- Automatic and manual modes - Microprocessor controlled - Limited to 6 cycles	- Automatic and manual modes - Microprocessor controlled - Limited to 6 cycles	- Manual mode - Recommends several cycles
Inhalation, Exhalation, and Pause Times	0 to 5 seconds, 0.2 second increments	0 to 5 seconds, 0.2 second increments	Human effort
Line Voltage Frequency	120-240V universal 50/60 Hz	120-240V universal 50/60 Hz	Non-powered
Indications	For use on any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube.	For use on any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube.	Intended for use as a positive expiratory pressure (PEP) device. Indication for use: For use as a single patient use, hand-held secretion clearance and lung expansion device that creates vibratory positive expiratory pressure when a patient exhales through the device.

Summary:

The Vital Cough with flutter is substantially equivalent to the Vital Cough cleared device cleared under K120277 based on intended use, comparative testing, frequency and waveform. The MI/E design is in both devices. The added flutter feature has the same indication for use to clear secretions as the original Vital Cough and the Acapella. The pressure and flow differences are due to the Vital Cough MI/E activity. The flutter activity is substantially equivalent. The Vital Cough with flutter is a mechanical device driven by a fan. The Acapella is driven by human effort. The Vital Cough device does the work for the patient.

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

March 28, 2014

Lung Assist, Incorporation
Mr. Lewis Ward
Vice President Operations
4655 Kirkwood Court
Boulder, CO 80301

Re: K132988
Trade/Device Name: Vital Cough
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NHJ
Dated: February 11, 2014
Received: February 25, 2014

Dear Mr. Ward:

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.

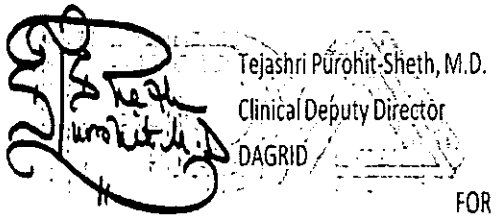
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132988

Device Name
Vital Cough

Indications for Use *(Describe)*
The Vital Cough is intended for use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in a hospital, institutional setting, or home use given adequate training. For use on adult or pediatric patients.

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)*

Anya C. Harry -S
2014.03.28
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