K132794

DEC 19 2013

ELECTROMED, INC.
Creating superior care through innovation®

SPECIAL 510(k) SUMMARY

This Special 510(k) Summary is submitted in accordance with 21 CFR 807.92.

Date prepared: September 4, 2013

SUBMITTER

Electromed, Inc.
502 Sixth Ave. NW
New Prague, MN 56071
Telephone: 952-758-9299

CONTACT INFORMATION

Chet Sievert
Director of Regulatory and Clinical Affairs
Telephone: 952-758-0384 direct 651-246-8621 cell
Fax: 888-877-3371
E-mail: csievert@electromed.com

DEVICE INFORMATION

Trade Name: SmartVest® Airway Clearance System, Model SQL
Common Name: Percussor, Powered-Electric

CLASSIFICATION

Regulation Number: 21 CFR 868.5665, Powered percussor
Product Code: BYI
Class: II
Panel: Anesthesiology

PREDICATE DEVICE

SmartVest® Airway Clearance System, Model TL; K053248

INDICATIONS FOR USE

The Indications for Use of the proposed modified device are identical to the legally marketed predicate device:

"The SmartVest® Airway Clearance System, Model SQL is designed to deliver high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The SmartVest® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport."

Corporate Headquarters
500 Sixth Ave. N.W.
New Prague, MN 56071
Phone: 952-758-9299
Fax: 952-758-1941
www.electromed.com

DEVICE DESCRIPTION

The modified Electromed SmartVest® Airway Clearance System, Model SQL is an electrically powered percussor device designed to deliver high frequency chest wall oscillation (HFCWO) to aid in freeing mucus deposits in the lungs in order to improve bronchial drainage under the order of a physician's prescription. The primary components of both the proposed modified and predicate HFCWO Airway Clearance Systems consist of an Air Pulse Generator, an Inflatable Vest, and an Air Hose that connects the Generator to the Inflatable Vest. The Air Pulse Generator produces small volumes of pressurized air pulses that are rapidly delivered to the Inflatable Vest via the Air Hose at a selected oscillatory frequency between 5-20 times per minute (Hz). The Inflatable Vest imparts the oscillatory air pulses as pressure forces to the patient's external chest wall. These pressurized air pulses promote transient increases in airflow within the lungs that loosens mucus sufficiently to facilitate expulsion by the patient when normal respiratory function is not capable.

DESCRIPTION OF THE CHANGES TO THE PREDICATE

Modifications were made to the Air Pulse Generator only. The modified generator was designed primarily to be smaller, quieter and lighter compared to the predicate. In addition, the following features were added to the predicate generator and two existing features were enhanced:

- Child-lock option on treatment settings
- Digital control of pressure settings
- On/Off switch
- Enhanced ramping feature
- Enhanced pause feature
- More "user friendly" graphic user interface

PERFORMANCE, FUNCTIONAL and SAFETY TESTING

Testing included:

- Comparison output performance testing; proposed modified vs. predicate (air pulse pressure, air pulse frequency and treatment time)
- Design verification testing (including software)
- Design validation testing (usability/human factors)
- IEC 60601-1 3rd edition, 60601-1-2 3rd edition, 60601-1-6 3rd edition, 60601-1-11 3rd edition and UL testing
- ASTM D4169-09 DC13, Standard Practice for Performance Testing of Shipping Containers and Systems

COMPLETION OF DESIGN CONTROL ACTIVITIES

Managing and documenting the design process of making modifications to the predicate device was performed under Electromed's Quality System which is compliant with 21 CFR 820. All modification and design activities were conducted in conformance to 21 CFR 820.30 Design Control including documentation of all design and development activities including risk analysis, project planning, design

requirements, design specifications, design transfer, design changes, verification and validation procedures and formal design reviews. These design control activities and testing ensured that the design output specifications met the design input requirements as well as meeting the device's intended use and the needs of the user population.

SUBTANTIAL EQUIVALENCE

A formal risk analysis of the proposed modified generator design revealed no new risks compared to the predicate generator design. All material changes were to a type of material that has been used in other legally marketed devices. Design verification testing, including software testing, demonstrated that the design output specifications met the design input requirements. Comparison performance testing of the proposed modified generator and the predicate generator including measurements of the air pulse pressure, air pulse frequency and treatment time demonstrated equivalence between the two devices. Usability/human factors testing demonstrated enhanced user operation with less potential for errors compared to the predicate. The modified design passed electromagnetic compatibility testing, electrical safety testing and UL testing.

The modified design does NOT change the device's operating principle or mechanism of action. Compared to the predicate, the proposed modified device has the identical indications for use, the same patient population, equivalent output performance and the same fundamental scientific technology which in total does not raise additional questions of safety or effectiveness thus meeting the definition of substantial equivalence.

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

December 19, 2013

Electromed, Incorporated
Mr. Chet Sievert
Director of Regulatory and Clinical Affairs
502 Sixth Avenue NW
NEW PRAGUE MN 56071

Re: K132794
Trade/Device Name: SmartVent Airway Clearance System, Model SQL
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: November 15, 2013
Received: November 20, 2013

Dear Mr. Sievert:

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.

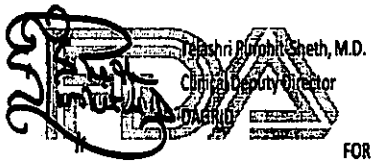
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5. Indications for Use Statement

Indications for Use Statement

510(k) Number: K132794

Device Name: SMARTVEST® AIRWAY CLEARANCE SYSTEM, MODEL SQL

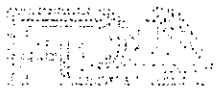
Indications for Use:

The SmartVest® Airway Clearance System, Model SQL is designed to deliver high frequency chest wall oscillation to promote airway clearance and improve bronchial drainage. The SmartVest® System is indicated when external chest manipulation is the physician's treatment of choice to enhance mucus transport.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Anya C. Harry -S
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