11/18/2022

Electromed, Inc.
Gregory Spurlock
Sr. Directory Regulatory & Quality Assurance
500 Sixth Ave NW
New Prague, Minnesota 56071

Re: K222496
Trade/Device Name: Electromed SmartVest Airway Clearance System
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: October 20, 2022
Received: October 21, 2022

Dear Gregory Spurlock:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

for James Lee, PhD
Division Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222496

Device Name
SMARTVEST® AIRWAY CLEARANCE SYSTEM, MODEL CLEARWAY

Indications for Use *(Describe)*
The SmartVest® Airway Clearance System, Model Clearway 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SPECIAL 510(k) SUMMARY

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

Date prepared: November 18, 2022

SUBMITTER

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CONTACT INFORMATION

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DEVICE INFORMATION

Trade Name: SmartVest® Airway Clearance System, Model Clearway 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 SQL; K132794

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 Clearway 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."

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DEVICE DESCRIPTION

The modified Electromed SmartVest® Airway Clearance System, Model Clearway is an electrically powered percussor device designed to deliver high frequency chest wall oscillation (HFCWO) to aid in freeing mucus deposits in the lungs to improve bronchial drainage and airway clearance 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 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 primary objective was to further reduce the size and weight of the generator to make it easier for the patient to lift and handle which has been frequently requested by Electromed's "Voice of the Customer" exercises.

The mechanical technological characteristics of the predicate and the proposed devices are mechanically identical. The mechanism of action of the predicate and the mechanism of action for the proposed device are the same. The air pulse pumps of the predicate and proposed devices are the same, they are driven by the same drive motor, and pressure output is controlled via the same pressure control valve. The mechanical differences identified between the predicate and proposed air pulse generator are primarily the device enclosure.

Modifications also consisted of updating the graphic user interface (GUI) by switching to a touchscreen to replace the predicate's micro dome momentary switches and LCD display. The switch to a new GUI was made because the current GUI is being discontinued and will no longer be available from the supplier. In addition, three features were added to the design of the predicate generator and five existing features were eliminated:

- The option to save a favorite treatment protocol was added. Selection of a "favorite" treatment protocol will automatically display on startup and allow the user to simply start their favorite treatment.
- The option to assign an emoji to each of the saved treatment protocols was added. On days the patient is feeling well, they can select a treatment protocol identified with a Good Day emoji. On days when the patient is feeling more congested, a protocol identified with a Bad Day emoji could be selected. Good/Bad Day labels allow patients to categorize treatments by the type of day for which they are best suited. The option to select NO emoji is also a valid option.
- The GUI's screen brightness adjustment was added that allows the user to fine tune the brightness of the display.
- The Main Power On/Off switch was eliminated based on user feedback. The modified Generator will go into a "sleep mode" when not in use and "awake" when prompted by simply engaging the touchscreen.
- Based on user feedback the user replaceable line fuse is no longer replaceable by the user, the line fuse was moved inside the generator.
- The replaceable internal air filter was eliminated because it was determined to be unnecessary for performance or reliability. Multiple unfiltered openings allowing air to enter the generator made the current filter ineffective. The competitive HFCWO device from Hill-Rom (K142482) is also designed with no air input filter.

- The cellular component for wireless reporting was eliminated with the availability of Bluetooth Low Energy remaining. The cellular option for wireless reporting was formerly implemented as "always on" and device settings were automatically communicated after completion of each therapy session. Users could formerly opt in to view the usage data however all data was viewable by Electromed for compliance reporting to insurers/payers. This change allows the user to enable or disable Bluetooth on the air pulse generator and control reporting by deciding when generator settings are communicated via an App on their phone or tablet.
- The option of bi-directional viewing of the GUI was eliminated because it was no longer applicable with the new redesigned smaller enclosure that is intended to be placed in only one position.

PERFORMANCE, FUNCTIONAL and SAFETY TESTING

Testing included:

- Comparison output performance testing of the proposed modified vs. the predicate generator including (air pulse pressure, air pulse frequency and treatment time.)
- Design verification testing (including software)
- Design validation testing (software/usability/human factors)
- UL Safety testing in accordance with the following standards were performed externally by UL:
    - IEC 60601-1:2012-Ed.3.1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
    - IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
    - IEC 60601-1-11:2015-Ed. 2.0 General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- Immunity and Emissions testing in accordance with IEC 60601-1-2:2014 + A1:2020 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests performed externally by Element.
- ASTM D4169-09 DC13, Standard Practice for Performance Testing of Shipping Containers and Systems performed externally by DDL.

COMPLETION OF DESIGN CONTROL ACTIVITIES

Managing and documenting the design process of making modifications to the predicate generator was performed under Electromed's Quality System which has been found by external audits to be compliant with 21 CFR 820 and certified to ISO 13485:2016. All modification and design activities were completed in accordance with Electromed work instruction EN-01 Design Control and 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 methods ensured that the design output specifications met the design input requirements for the proposed modified generator.

SUBSTANTIAL EQUIVALENCE

Comparative performance testing of the proposed modified generator and the predicate generator including measurements of the air pulse pressure, air pulse frequency and treatment time (known collectively as the generator's clinical performance output) was used to demonstrate equivalence

between the two generators. Testing was conducted on both the predicate and proposed Generators using multiple Inflatable Vests that included the smallest and the largest sizes using the full range of Generator settings for pressure and frequency. This testing employed acceptance criterion using a two-sample Kolmogorov-Smirnov hypothesis test with a 95% confidence level. The passing result of the hypothesis test with the 95% confidence level demonstrate the proposed device to be safe and effective across the range of settings and garment sizes.

Usability/human factors testing was performed on the proposed modified generator and revealed no new usability issues or risks.

A formal risk analysis of the proposed modified generator design revealed no new risks compared to the predicate generator design. Specifically, the software cyber security risk assessment identified no new risks or cyber security issues associated with the new software, feature additions or eliminations.

The materials used in the proposed modified generator are the same materials as used in the predicate generator except for the patient contact area of the new touchscreen user interface being commercial hardened glass rather than plastic.

The proposed modified generator design uses the same safety and output performance components as the predicate generator i.e., the same air pressure valve, same air pump mechanism, same pump drive motor which in total do NOT change the generator's operating principle or mechanism of action.

Design verification testing, including software testing, demonstrated that the design output specifications met the design input requirements of the proposed modified generator. The modified design passed electromagnetic compatibility (EMC) testing, electrical safety testing and UL testing. The methods and acceptance criteria used to establish equivalence were the same as the predicate generator and are relevant to the change under review.

Compared to the predicate, the proposed modified generator has the identical indications for use, the same intended patient population, substantially equivalent output performance and the same fundamental scientific technology which in total do not raise additional questions of safety or effectiveness thus meeting the definition of substantial equivalence.