December 19, 2024

Synchrony Medical Ltd.
Anat Shani
CEO
8 Ariel Sharon
Or Yehuda, IL 6037607
Israel

Re: K242063
Trade/Device Name: LibAirty Airway Clearance System
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: SDS
Dated: December 17, 2024
Received: December 17, 2024

Dear Anat Shani:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242063

Device Name

LibAirty Airway Clearance System

Indications for Use *(Describe)*

The LibAirty Airway Clearance System is intended to provide airway clearance therapy and promote bronchial drainage when external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.

The LibAirty Airway Clearance System is intended for hospital, home, and clinic use.

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.**

# 510(K) Summary

## Synchrony Medical LibAirty Airway Clearance System

**Submitter**

Synchrony Medical Ltd.
8 Ariel Sharon
Or Yehuda, 6037607
Israel
Phone: +972-74-739-0681

**Contact Person:**

Anat Shani, CEO

anat.s@synchrony-medical.com

Phone: +972 545221922

**Date Prepared:** July 09, 2024

**Name of Device:** LibAirty™ Airway Clearance System

**Common or Usual Name:** Airway clearing device

**Classification Name:** Powered percussor

**Regulation:** 21 CFR §868.5665

**Regulatory Class:** Class II

### Predicate Device

The Vest Airway Clearance System by Hill-Rom Services Private Limited, cleared under K142482.

### Device Description

The LibAirty Airway Clearance System is designed to assist in the loosening and elimination of mucus from the lungs. It consists of a vest with inflatable chambers, connected to a control unit (equipped with an air compressor) that inflates and deflates the vest in a pre-defined cycle, and a mobile application.

The LibAirty Airway Clearance System was designed to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment, while using an inflatable vest connected to an air supply unit.

The LibAirty Airway Clearance System is designed to promote breathing at different volumes, as the inflatable vest applies oscillating pressure on the chest and back, to augment peripheral and tracheal mucus movement towards the airway opening. The system's mode of operation is inspired by the principles of the Autogenic Drainage (AD) airway clearance technique, in which adjusting the depth and location of lung volumes during respiration generates shearing forces induced by airflow which loosen, mobilize, and move secretions (i.e., mucus) from the peripheral towards the central airways. Once the mucus reaches the larger airways, it can be expelled through coughing.

The LibAirty™ Airway Clearance System is a mobile, non-sterile, reusable, single patient use device, operated by mains power supply only.

The LibAirty™ Airway Clearance System consists of:

- A control unit equipped with an air compressor that delivers air at regulated pressures to the vest and includes a display screen and operation buttons allowing the user to adjust therapy settings and manage device operation.
- An inflatable vest (available in different sizes) that is fastened around the chest and consists of several air chambers.
- A hose bundle that transfers the air from the control unit to the vest's chambers.
- A Mobile Application (App) that is used to operate the system and provide instructions.

**Intended Use / Indications for Use**

The LibAirty™ Airway Clearance System is intended to provide airway clearance therapy and promote bronchial drainage when external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging.

The LibAirty™ Airway Clearance System is intended for hospital, home, and clinic use.

## Summary of Technological Characteristics

The LibAirty Airway Clearance System consists of an inflatable vest, a control unit, and a mobile application. The vest is comprised of several air chambers that apply oscillating pressure on the chest and back and is connected via a hose bundle to the control unit (equipped with an air compressor) that inflates and deflates the vest in a pre-defined cycle.

The LibAirty Mobile App is connected to the LibAirty Control Unit via Bluetooth communication and is used to operate the treatment and provide instructions.

## Predicate Device Comparison

The LibAirty™ Airway Clearance System is substantially equivalent to the predicate device, The Vest® Airway Clearance System (K142482).

The LibAirty Airway Clearance System and The Vest Airway Clearance System were designed to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment, while using an inflatable vest connected to an air supply unit, based on different airway clearance techniques. As a result of this difference, the physical characteristics of both devices are not identical, such as differences in the dimensions and weight, different vest design, etc. However, the differences do not raise new questions of safety or effectiveness.

A table comparing the key features of the subject and predicate device is provided below.

## Substantial Equivalence Comparison Table

| Feature | LibAirty Airway Clearance System (subject device) | The Vest Airway Clearance System (predicate device, K142482) | Comments |
|---|---|---|---|
| **Classification** | Powered-electric Percussor 868.5665 | | Identical. |
| **Intended Use/ Indications for Use** | The LibAirty Airway Clearance System is intended to provide airway clearance therapy and promote bronchial drainage when external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion | The Vest Airway Clearance System is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of | Similar.<br>The minor differences are wording adjustments which do not impact the intended purpose or the clinical use of LibAirty Airway Clearance System in comparison to its predicate device. |

| Feature | LibAirty Airway Clearance System (subject device) | The Vest Airway Clearance System (predicate device, K142482) | Comments |
|---|---|---|---|
| | clearance, or the presence of atelectasis caused by mucus plugging. | Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Vest Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation. | |
| **User Population** | Adult patients | Pediatric to Geriatrics patients | Similar. There are no new concerns of safety or effectiveness for the subject device's user population in comparison to the predicate device, which has broader patient range. |
| **Environment of Use** | The LibAirty Airway Clearance System is intended for hospital, home, and clinic use. | Critical care, in-patient acute care, extended care and skilled nursing facility care, home care, outpatient / ambulatory care and pulmonary diagnostic (bronchoscopy) laboratory | Similar. The environment of use of the subject device is similar to the predicate device, which has a broader range of environments. |
| **Technological Characteristics** | Vest with air chambers that are filled by an air compressor, connected by hoses.<br>An inflatable vest comprised of six air chambers that apply oscillating pressure on the chest and back. Available in various sizes and includes adjustment straps for a snug fit.<br>AC/DC powered<br>Mobile App connected via Bluetooth to control the treatment flow and provide instructions. | Vest with air chambers that are filled by an air generator, connected by hoses.<br>An inflatable vest surrounding the patient's torso, available in various styles and sizes for snug and evenly-distributed fit.<br>AC/DC powered<br>Bluetooth for data transmission only | Similar<br>Both the subject device and the predicate device were designed to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment, while using an inflatable vest connected to an air supply unit. There are no new concerns of safety or effectiveness for the subject device due to the differences in the technological characteristics. |
| **External manipulation of the chest** | Yes | Yes | Identical |

| Feature | LibAirty Airway Clearance System (subject device) | The Vest Airway Clearance System (predicate device, K142482) | Comments |
|---|---|---|---|
| **Principle of Operation / Technology** | An inflatable vest comprised of several air chambers that apply oscillating pressure on the chest and back to promote breathing at different lung volumes. Adjusting the depth and location of lung volumes during respiration generates shearing forces induced by airflow which loosen, mobilize, and move secretions (i.e., mucus) from the peripheral towards the central airways. Once the mucus reaches the larger airways, it can be expelled through coughing. | The Vest Airway Clearance System consists of an inflatable vest attached to an air generator that rapidly inflates and deflates the vest (High frequency chest wall oscillation). This causes the chest wall to be gently compressed and released, which creates airflow within the lungs. This process moves the mucus toward the large airways where it can be cleared by coughing or suctioning. | Identical results using different principles.<br>The LibAirty Airway Clearance System is designed to promote breathing at different volumes, based on the principles of the Autogenic Drainage (AD) airway clearance technique.<br>The Vest Airway Clearance System uses high frequency chest wall oscillations.<br>There are no new concerns of safety or effectiveness for the subject device due to the differences in the technology/ principle of operation. |
| **Treatment Modes** | 7 pre-sets pressure levels<br><br>Adjustable treatment parameters (time and pressure level)<br><br>Mobile App (connected via Bluetooth to control the treatment flow and provide instructions) | Manual<br><br>Adjustable treatment parameters (frequency, pressure and time)<br><br>Cough Pause (Reminds patients to cough) | Similar.<br>The subject device principle of operation is based on Autogenic Drainage (AD) airway clearance technique while the predicate device uses high frequency chest wall oscillations Both device's software enables patients to adjust the treatment parameters.<br>Comparative clinical study did not raise any new concerns of safety or effectiveness for the subject device due to the minor differences reflected in the treatment modes. |
| **Acoustic energy** | Up to 65 dBA @ 1 m | 82.8 dBA @ 1 m | Similar.<br>The acoustic energy limit of the subject device is lower than the predicate device. Thus, no new concerns of safety or effectiveness for the subject device were raised. |
| **Major Components** | Control Unit (equipped with Air Compressor)<br>Inflatable Vest<br>Hose Bundle<br>Mobile Application | Air Pulse Generator<br>Inflatable garments of various styles and sizes<br>Connecting hose | Similar<br>Both the subject device and the predicate device were designed to provide airway clearance therapy, while using an inflatable vest connected to an air supply unit. There were no new concerns of safety or effectiveness for the subject device due to the minor differences. |
| **Dimensions (H x W x D)** | 198 x 340 x 240 mm | 241 x 330 x 241 mm | Similar.<br>The differences between the subject device and the predicate device are minor and do not raise any new concerns of safety or effectiveness. |
| **Weight** | Control Unit - 4.5 kg<br>Vest - Less than 1.2 Kg (depends on the vest size) | Air Pulse Generator - 8 kg<br>Vest - 1.0 Kg | Similar.<br>The predicate device's air supply unit is heavier than the subject device. There are no new concerns |

| Feature | LibAirty Airway Clearance System (subject device) | The Vest Airway Clearance System (predicate device, K142482) | Comments |
|---|---|---|---|
| | | | of safety or effectiveness due to the differences in devices' weight. |
| **Electrical Specifications** | 100 – 240 VAC, 50/60 Hz 1.5A 7A @ 12VDC / 90W | 100 – 230 VAC, 50 / 60 Hz 3.4 A @ 100 VAC / 2.0 A @ 230 VAC | Similar. The differences between the subject device and the predicate device are minor. Thus, there are no new concerns of safety or effectiveness for the subject device. |
| **Biocompatibility** | No direct patient contact. Patient wears an undergarment | No direct patient contact. Patient wears an undergarment | Identical |
| **Operating conditions** | Temp – 50 to 86º F (10 to 30°C)<br>Relative Humidity – 30%-85%, non-condensing<br>Atmospheric pressure – 70 to 106 kPa | Temp – 41 to 95º F (5 to 35°C)<br>Relative Humidity – 15 to 95%, non-condensing<br>Atmospheric pressure – 70 to 106 kPa | Similar. The differences between the subject device and the predicate device are minor and do not raise any new concerns of safety or effectiveness for the subject device. |
| **Electrical safety** | IEC 60601-1<br>IEC 60601-1-11 | UL/EN/IEC 60601-1 and CAN/CSA CAN/CSA C22.2 No. 60601-1 | Similar<br>Both subject device and predicate device are in compliance with FDA recognized consensus electrical safety standards. As both devices are intended to be used in home environment (among others), the subject device was tested according to IEC 60601-1-11 (Req. for ME equipment and medical electrical systems used in the home healthcare environment) as well. Thus, there are no new concerns of safety or effectiveness for the subject device. |
| **Environmental conditions** | Temperature -4°F to 158°F (-20°C to 70°C)<br>Relative humidity of 10% to 93% non-condensing<br>Atmospheric pressure of 19 to 106 kPa | Temp – -4 to 140°F (-20°C to 60°C)<br>Relative Humidity – 15 to 90% non-condensing<br>Atmospheric pressure – 50 to 106 kPa | Similar. The differences between the subject device and the predicate device are minor and do not raise any new concerns of safety or effectiveness for the subject device. |

**Non-Clinical Performance Data**

The LibAirty Airway Clearance System went through a series of verification and validation testing to demonstrate that it meets the overall predefined design input requirements and specifications.

This testing evaluated the ability of the LibAirty System to meet the system's specifications in accordance with its proposed intended use, as well as general dimensional, mechanical, electrical, functional, and labeling requirements of the system.

The nonclinical testing of the LibAirty Airway Clearance System included the following

- Design Verification testing, such as: Treatment Flow - system level verification, System Pneumatics Verification, Maximal Forces Applied by LibAirty Airway Clearance System verification, etc.
- Labeling Verification
- LibAirty system Lifetime and durability Verification
- Software/ Firmware validation, including Cybersecurity (IEC 62304)
- Electrical Safety (IEC 60601-1 and (IEC 60601-1-11)
- Electromagnetic Compatibility (IEC 60601-1-2)
- Electromagnetic Immunity (IEC TS 60601-4-2)
- Wireless Coexistence (IEEE ANSI C63.27)
- Human Factors Validation Usability study, in accordance with FDA Guidance - Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)

Note:
Biocompatibility – There are no patient contacting materials.
The LibAirty Airway Clearance System's vest is intended to be worn by the user over light clothing, similarly to the predicate device. Hence, there is no direct or indirect contact between the garment materials and the patient's skin.

In all instances, the LibAirty Airway Clearance System functioned as intended and the results were as expected and met the acceptance criteria.

**Clinical Performance Data**

In order to support the claim that the LibAirty Airway Clearance System is substantially equivalent to The Vest Airway Clearance System, Synchrony Medical performed a comparative clinical study in subjects with bronchiectasis to demonstrate that the LibAirty Airway Clearance System is non-inferior to high frequency chest wall oscillation (HFCWO) therapy applied by The Vest, the predicate device.

The primary effectiveness endpoint of the study compared the sputum weight as measured post LibAirty treatment with the sputum weight as measured post The Vest treatment.

The study was a randomized controlled two-sequence crossover study, and performed at the Medical University of South Carolina, Charleston, South Carolina.

Subjects older than 21 years of age, with bronchiectasis who met the inclusion criteria were enrolled and randomly allocated to one of the two treatment sequences: LibAirty (Visit 1) followed by the Vest (Visit 2) or The Vest (Visit 1) followed by the LibAirty (Visit 2) in a 1:1 ratio. A third study visit (Visit 3) was performed using the LibAirty Airway Clearance System in conjunction with a nebulizer, as defined as part of the study's secondary endpoints.

There were 28 subjects who completed the entire study, including Visit 3.

A significant difference was found between the weight of sputum expectorated with LibAirty system and the weight of sputum expectorated with The Vest, where treatment with the LibAirty system produced a greater sputum weight. The mean difference in sputum weights (LibAirty – The Vest) is 3.312 with a 95% CI of (2.002, 4.621) and a p-value < 0.0001. These results mean that not only non-inferiority (NI) was established but superiority was also attained. These findings were not affected by treatment arm, sequence or period.

Additionally, participants completed a system evaluation questionnaire, where the reported level of satisfaction with LibAirty was higher compared to The Vest.

No Serious Adverse Event (SAE) or Unanticipated Adverse Device Effect (UADE) occurred throughout the study.

This study showed a superior performance of the LibAirty system when compared to The Vest.

Altogether, these findings suggest that the LibAirty Airway Clearance System is an effective, safe, and easy to use airway clearance device and support the claim that the LibAirty Airway Clearance System is substantially equivalent to its predicate device, The Vest Airway Clearance System.

**Conclusions**

The LibAirty™ Airway Clearance System is substantially equivalent The Vest Airway Clearance System. The LibAirty™ Airway Clearance System and its predicate device have the same indication for use and are both designed for the same intended use and target population. The minor technological differences between the LibAirty™ Airway Clearance System and its predicate device do not raise any new issue of safety or effectiveness. Performance data demonstrate that the LibAirty™ Airway Clearance System

is substantially equivalent as The Vest Airway Clearance System. Thus, the LibAirty™ Airway Clearance System is substantially equivalent to The Vest Airway Clearance System.

## Substantial Equivalence Comparison Table

| Feature | LibAirty Airway Clearance System (subject device) | The Vest Airway Clearance System (predicate device, K142482) | Comments |
|---|---|---|---|
| **Classification** | Powered-electric Percussor 868.5665 | | Identical. |
| **Intended Use/ Indications for Use** | The LibAirty Airway Clearance System is intended to provide airway clearance therapy and promote bronchial drainage when external manipulation of the thorax is the physician's choice of treatment. It is indicated for patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging. | The Vest Airway Clearance System is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice or treatment. Indications for this form of therapy are described by the American Association of Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy. According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Vest Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for the purposes of collecting mucus for diagnostic evaluation. | Similar.<br>The minor differences are wording adjustments which do not impact the intended purpose or the clinical use of LibAirty Airway Clearance System in comparison to its predicate device. |
| **User Population** | Adult patients | Pediatric to Geriatrics patients | Similar.<br>There are no new concerns of safety or effectiveness for the subject device's user population in comparison to the predicate device, which has broader patient range. |
| **Environment of Use** | The LibAirty Airway Clearance System is intended for hospital, home, and clinic use. | Critical care, in-patient acute care, extended care and skilled nursing facility care, home care, outpatient / ambulatory care and pulmonary diagnostic (bronchoscopy) laboratory | Similar.<br>The environment of use of the subject device is similar to the predicate device, which has a broader range of environments. |
| **Technological Characteristics** | Vest with air chambers that are filled by an air compressor, connected by hoses.<br>An inflatable vest comprised of six air chambers that apply oscillating pressure on the chest and back. Available in various sizes and includes | Vest with air chambers that are filled by an air generator, connected by hoses.<br>An inflatable vest surrounding the patient's torso, available in various styles and sizes for snug and evenly-distributed fit. | Similar<br>Both the subject device and the predicate device were designed to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment, while using an inflatable vest connected to an air |

| Feature | LibAirty Airway Clearance System (subject device) | The Vest Airway Clearance System (predicate device, K142482) | Comments |
|---|---|---|---|
| | adjustment straps for a snug fit.<br>AC/DC powered<br>Mobile App connected via Bluetooth to control the treatment flow and provide instructions. | AC/DC powered<br>Bluetooth for data transmission only | supply unit. There are no new concerns of safety or effectiveness for the subject device due to the differences in the technological characteristics. |
| **External manipulation of the chest** | Yes | Yes | Identical |
| **Principle of Operation / Technology** | An inflatable vest comprised of several air chambers that apply oscillating pressure on the chest and back to promote breathing at different lung volumes. Adjusting the depth and location of lung volumes during respiration generates shearing forces induced by airflow which loosen, mobilize, and move secretions (i.e., mucus) from the peripheral towards the central airways. Once the mucus reaches the larger airways, it can be expelled through coughing. | The Vest Airway Clearance System consists of an inflatable vest attached to an air generator that rapidly inflates and deflates the vest (High frequency chest wall oscillation). This causes the chest wall to be gently compressed and released, which creates airflow within the lungs. This process moves the mucus toward the large airways where it can be cleared by coughing or suctioning. | Identical results using different principles.<br>The LibAirty Airway Clearance System is designed to promote breathing at different volumes, based on the principles of the Autogenic Drainage (AD) airway clearance technique.<br>The Vest Airway Clearance System uses high frequency chest wall oscillations.<br>There are no new concerns of safety or effectiveness for the subject device due to the differences in the technology/ principle of operation. |
| **Treatment Modes** | 7 pre-sets pressure levels<br>Adjustable treatment parameters (time and pressure level)<br>Mobile App (connected via Bluetooth to control the treatment flow and provide instructions) | Manual<br>Adjustable treatment parameters (frequency, pressure and time)<br>Cough Pause (Reminds patients to cough) | Similar.<br>The subject device principle of operation is based on Autogenic Drainage (AD) airway clearance technique while the predicate device uses high frequency chest wall oscillations Both device's software enables patients to adjust the treatment parameters.<br>Comparative clinical study did not raise any new concerns of safety or effectiveness for the subject device due to the minor differences reflected in the treatment modes. |
| **Acoustic energy** | Up to 65 dBA @ 1 m | 82.8 dBA @ 1 m | Similar.<br>The acoustic energy limit of the subject device is lower than the predicate device. Thus, no new concerns of safety or effectiveness for the subject device were raised. |
| **Major Components** | Control Unit (equipped with Air Compressor)<br>Inflatable Vest<br>Hose Bundle<br>Mobile Application | Air Pulse Generator<br>Inflatable garments of various styles and sizes<br>Connecting hose | Similar<br>Both the subject device and the predicate device were designed to provide airway clearance therapy, while using an inflatable vest connected to an air supply unit. There were no new concerns of safety or effectiveness for the |

| Feature | LibAirty Airway Clearance System (subject device) | The Vest Airway Clearance System (predicate device, K142482) | Comments |
|---|---|---|---|
| | | | subject device due to the minor differences. |
| **Dimensions (H x W x D)** | 198 x 340 x 240 mm | 241 x 330 x 241 mm | Similar.<br>The differences between the subject device and the predicate device are minor and do not raise any new concerns of safety or effectiveness. |
| **Weight** | Control Unit - 4.5 kg<br>Vest - Less than 1.2 Kg (depends on the vest size) | Air Pulse Generator - 8 kg<br>Vest - 1.0 Kg | Similar.<br>The predicate device's air supply unit is heavier than the subject device. There were no new concerns of safety or effectiveness raised due to the differences in devices' weight. |
| **Electrical Specifications** | 100 – 240 VAC, 50/60 Hz 1.5A<br>7A @ 12VDC / 90W | 100 – 230 VAC, 50 / 60 Hz<br>3.4 A @ 100 VAC / 2.0 A @ 230 VAC | Similar.<br>The differences between the subject device and the predicate device are minor. Thus, no new concerns of safety or effectiveness for the subject device were raised. |
| **Biocompatibility** | No direct patient contact.<br>Patient wears an undergarment | No direct patient contact.<br>Patient wears an undergarment | Identical |
| **Operating conditions** | Temp – 50 to 86º F (10 to 30°C)<br>Relative Humidity – 30%-85%, non-condensing<br>Atmospheric pressure – 70 to 106 kPa | Temp – 41 to 95º F (5 to 35°C)<br>Relative Humidity – 15 to 95%, non-condensing<br>Atmospheric pressure – 70 to 106 kPa | Similar.<br>The differences between the subject device and the predicate device are minor. Thus, no new concerns of safety or effectiveness for the subject device were raised. |
| **Electrical safety** | IEC 60601-1<br>IEC 60601-1-11 | UL/EN/IEC 60601-1 and CAN/CSA CAN/CSA C22.2 No. 60601-1 | Similar<br>Both subject device and predicate device are in compliance with FDA recognized consensus electrical safety standards. As both devices are intended to be used in home environment (among others), the subject device was tested according to IEC 60601-1-11 (Req. for ME equipment and medical electrical systems used in the home healthcare environment) as well. Thus, no new concerns of safety or effectiveness for the subject device were raised. |
| **Environmental conditions** | Temperature -4°F to 158°F (-20°C to 70°C)<br>Relative humidity of 10% to 93% non-condensing<br>Atmospheric pressure of 19 to 106 kPa | Temp – -4 to 140°F (-20°C to 60°C)<br>Relative Humidity – 15 to 90% non-condensing<br>Atmospheric pressure – 50 to 106 kPa | Similar.<br>The differences between the subject device and the predicate device are minor. Thus, no new concerns of safety or effectiveness for the subject device were raised. |