March 22, 2024

Baxter Healthcare Corportation
Steven Co
Regulatory Affairs Manager
One Baxter Parkway
Deerfield, Illinois 60015

Re: K233441
Trade/Device Name: The Vest APX System (PVAPX1)
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: BYI
Dated: February 28, 2024
Received: February 28, 2024

Dear Steven Co:
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.

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,

John S. Bender -S

Digitally signed by John S. Bender -S
Date: 2024.03.22 16:44:18 -04'00'

for Ethan Nyberg, Ph.D.
Assistant 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

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)*
K233441

Device Name
The Vest APX System (PVAPX1)

Indications for Use *(Describe)*

The Vest APX System is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. 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 APX 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.

The Vest APX System may be used for the pediatric population (6 months and older) to geriatric population.

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.

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Baxter

510(k) Summary

Submitter:

Company Name:	Baxter Healthcare Corporation
Address:	One Baxter Parkway Deerfield, Illinois 60015
Telephone Number:	1-800-422-9837
Prepared and Submitted by:	Steven Co
Title:	Regulatory Manager, Global Regulatory Affairs
Contact Person:	Steven Co
Title:	Regulatory Manager, Global Regulatory Affairs
Telephone:	224-948-1812
Email:	Steven_Co@baxter.com
Date Prepared:	March 22, 2024

IDENTIFICATION OF THE DEVICE:

Common Name: Powered Percussor
Trade/Device Name: The Vest APX System
Classification Panel: Anesthesiology
Regulation Number: 21 CFR 868.5665
Regulation Name: Percussor, Powered-Electric
Regulatory Class: Class II
Product Code: BYI

Table 1. Model Number(s) for The Vest APX System

Model Number	Name
PVAPX1	The Vest APX System

PREDICATE DEVICE:

Table 2. Predicate Device(s)

Device	Company	Predicate 510(k)	Clearance Date
The Vest Airway Clearance Systems	Hill-Rom Services Private Limited	K142482	May 7, 2015

DESCRIPTION OF THE DEVICE:

The Vest APX System is a high-frequency chest wall oscillation device designed to be used in a wide variety of settings for enhancing the mobilization of bronchial secretions. The primary components of The Vest APX System consist of a control unit, hoses, and an inflatable garment. Oscillating positive pressure air pulses are applied to the garment by the control unit. The Blower provides the baseline pressure to the system. The user will input the different intensity from 1 -10 on the Graphical User Interface (GUI) and the blower will produce different static pressure based on speed. The air pulse generator (APG) provides the air pulsations (oscillations) based on the frequency input (ranging from 5 to 20 Hertz) provided by user via the GUI. The APG is driven by the Brushless Direct Current (BLDC) motor.

The resulting pressure pulses cause the garment to inflate and deflate against the chest of the patient, creating high-frequency chest wall oscillation and mobilization of bronchial secretions. This form of airway clearance therapy is referred to as high-frequency chest wall oscillation (HFCWO).

INDICATIONS FOR USE:

The Vest APX System is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. 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** APX 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.

The Vest APX System may be used for the pediatric population (6 months and older) to geriatric population.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

Baxter Healthcare Corporation has made modifications to the predicate device, The Vest Airway Clearance Systems. The subject device, The Vest APX System, has the same technological characteristics as the predicate device. The proposed modifications to the subject device do not raise different questions of safety and effectiveness. A summary of the technological characteristics of the subject device in comparison to those of the predicate device is provided in Table 3.

Table 3. Device Comparison

Features	Predicate Device The Vest Airway Clearance Systems Cleared under K142482	Subject Device The Vest APX System	Assessment of Differences
Manufacturer	Hill-Rom Services Private Limited	Same	N/A
Product Code	BYI	Same	N/A
Classification Name	Percussor, Powered-Electric	Same	N/A
Regulation Number	868.5665	Same	N/A
Intended Use	The Vest Airway Clearance System was developed to provide effective Airway Clearance Therapy. The system consists of an inflatable garment attached to an Air Pulse Generator that rapidly inflates and deflates the inflatable garment. 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. This type of Airway Clearance Therapy is referred to as High Frequency Chest Wall Oscillation (HFCWO).	Same	N/A
Indications for Use	The Vest Airway Clearance System, Model 105 & Model 205 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	The Vest APX System is intended to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient	Similar The subject device removed outdated AARC clinical practice guidelines reference included in the predicate indications for use. The subject device clarifies the intended patient population.

Table 3. Device Comparison

Features	Predicate Device The Vest Airway Clearance Systems Cleared under K142482	Subject Device The Vest APX System	Assessment of Differences
	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.	is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, The Vest APX 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. The Vest APX System may be used for the pediatric population (6 months and older) to geriatric population.	
Environments of Use	Acute care, extended care and skilled nursing facility care, home care, outpatient /ambulatory care, pulmonary diagnostic (bronchoscopy) laboratory.	Same	N/A
Intended Population	Pediatric to geriatric population	Pediatric population (6 months and older) to geriatric population.	Similar The subject device specifies the intended pediatric population.
Standard Compliance	21 CFR 820 ISO 13485: 2016 ISO 14971: 2019	21 CFR 820 ISO 13485: 2016 ISO 14971: 2019	Similar

Table 3. Device Comparison

Features	Predicate Device The Vest Airway Clearance Systems Cleared under K142482	Subject Device The Vest APX System	Assessment of Differences
	IEC 60601-1: 2005 + A1: 2012 IEC 60601-1-2: 2014 IEC 60601-1-6: 2010 + A1: 2013 IEC 62366-1: 2015 IEC 60601-1-11: 2015 IEC 62304: 2006 + A1: 2015 ANSI/AAMI ES60601-1:2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012 ANSI/AAMI HA60601-1-11:2015 47 CFR FCC Part 15B:2012 (CLASS B) ISO 10993-1:2018 ISO 15223-1:2021 ISO 20417:2021	IEC 60601-1: 2005 + A1: 2012 + A2:2020 IEC 60601-1-2: 2014 + A1:2020 IEC 60601-1-6: 2010 + A1:2013 + A2:2020 IEC 62366-1:2015 + A1:2020 IEC 60601-1-11:2015+ A1:2020 IEC 62304: 2006 + A1 :2015 ANSI/AAMI ES60601-1:2005/A2:2021 ANSI/AAMI HA60601-1-11:2015/A1:2021 47 CFR FCC Part 15 Subpart B 47 CFR FCC Part 15 Subpart C 47 CFR FCC Part 15 Subpart E IEEE/ANSI C63.27: 2017 47 CFR §2.1091 ISO 10993-1:2018 ISO 15223-1:2021 ISO 20417:2021	
Sterile	No	Same	N/A
Non-Pyrogenic	Yes	Same	N/A
Single Use	No	Same	N/A
Configuration for home care	Model 105 includes a carrying case.	Model PVAPX1HC includes a carrying case	Same
Configuration for acute care	Model 205 includes a cart and advanced software settings for use by a physician or	Model PVAPX1AC includes a cart and advanced software settings for use by a physician or	Same

Table 3. Device Comparison

Features	Predicate Device The Vest Airway Clearance Systems Cleared under K142482	Subject Device The Vest APX System	Assessment of Differences
	professional health care provider	professional health care provider	
Generator	Air Pulse Generator	Same	N/A
Hose	Connecting hose (60") mechanical interlock/friction fit	Connecting hose (60"). Hose to control unit uses magnetic force connection. Hose to garment uses friction fit	Similar The different connection mechanism allows an easier connection option for users with limited dexterity.
Garment Offerings	Chest (Permanent) Full Vest (Permanent / SPU / C3) Wrap Vest (Permanent / SPU)	Full Vest (Disposable/Reusable) Wrap Vest (Disposable/Reusable)	Similar The difference is consolidation of the garments types offered, the size range options is the same.
Technology of Oscillations	Pneumatic - air driven by control unit inflates/deflates the garment air bladder	Same	N/A
Electrical Specifications	100 – 230 VAC, 50 / 60 Hz 3.4 A @ 100 VAC / 2.0 A @ 230 VAC Power plug – NEMA 1-15P (2 pin)	100 – 240 VAC, 50 / 60 Hz 3.5 A @ 100 VAC Power plug – NEMA 1-15P (2 pin)	Similar
Connectivity	Bluetooth	Wi-Fi USB	Similar

DISCUSSION OF NONCLINICAL TESTS:

Nonclinical testing has been performed to demonstrate that The Vest APX System is substantially equivalent to The Vest Airway Clearance Systems. These tests included:

- Comparative pressure testing for the subject and predicate garments
- Usability testing per IEC 62366-1:2015 + A1:2020
- Additional comparative pressure testing for the 16"-19" Child XS Garment with the subject and predicate devices

Performance Data:

The Vest APX System meets the following electromagnetic compatibility and safety standards:

- IEC 60601-1-2 Edition 4.1 2020-09, "Medical Electrical Equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2]
- IEC 60601-1-11 Edition 2.1 2020-07, "Medical Electrical Equipment-Part 1-11 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"

Biocompatibility:

The Vest APX System complies with the requirements of ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.

CONCLUSION:

Substantial equivalence between The Vest APX System and the referenced predicate, The Vest Airway Clearance Systems, is demonstrated by:

- Substantially equivalent indications statements
- Identical intended use statements
- Substantially equivalent technological characteristics:
  - Both employ air pulse generators
  - Both treat the same anatomic locations of the thorax
  - Both provide high frequency chest wall oscillations

The Vest APX System is substantially equivalent to The Vest Airway Clearance Systems. The differences in the control unit, garment and hose designs do not introduce any new risks or raise any new questions of safety or effectiveness.