October 24, 2019

Smiths Medical
% Dawn Norman
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

Re: K181660
Trade/Device Name: acapella Choice Blue Vibratory PEP Device
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: Class II
Product Code: BWF
Dated: September 20, 2019
Received: September 23, 2019

Dear Ms. Norman:

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,

for

Michael Ryan
Division Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181660

Device Name
acapella® Choice Blue Vibratory PEP Device

Indications for Use *(Describe)*
The Smiths Medical acapella® Choice Blue Vibratory PEP Device is intended for use as a Positive Expiratory Pressure (PEP) device for adults and children (5 years and up). It may also be used simultaneously with nebulized aerosol drug delivery.

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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Date of Preparation:	October 23, 2019
Submitter:	Smiths Medical 6000 Nathan Lane North Minneapolis, MN 55442 USA
Establishment Registration Number:	3012307300
Company Contact (Primary):	Dawn N. Norman MRC|X 6075 Poplar Avenue, Suite 500 Memphis, TN 38119 01-618-604-3064
Trade Name(s):	Incentive Spirometer
Device Name(s):	acapella® Choice Blue Vibratory PEP Device
Device Classification:	Class II
Regulation Number and Product Codes:	21 CFR § 868.5690 / BWF Spirometer, Therapeutic (Incentive)

Primary Predicate Device

Primary Predicate Device Name / Original 510(k) Owner	Product Code / Regulation	FDA 510k Number / Clearance Date
acapella® DH Original 510(k) owner: DHD Healthcare	BWF 21 CFR 868.5690	K002768 September 6, 2000

General Device Description

The subject and predicate acapella® devices are within Smiths Medical's product family for a therapeutic spirometer hand-held vibratory positive expiratory pressure (PEP) device provided to the end-user as a non-sterile, single patient use. The subject device helps aid in the mobilization and expectoration of secretions that accumulate in the lungs of adult and pediatric users who may have Cystic Fibrosis, COPD, asthma, including lung diseases with secretory problems, and patients with atelectasis.

The subject device provides PEP therapy to a patient by producing airflow vibrations that can be delivered in any position to effectively mobilize secretions, open airways and deliver medication (nebulization). These devices have been found to give independence to patients with chronic respiratory diseases, as the therapy can be done at the patient's convenience without the need for clinical assistance.

Principle of Operation

The *acapella® Choice Blue Vibratory PEP Device* using a non-return valve that upon patient exhalation will create positive end expiratory pressure and oscillations. The device is adjustable to different frequencies. Rotation of the knob between the limits of the cam surfaces allows the

physician or clinician to set a desired frequency and pressure for an individual patient or user, and the desired frequency and pressure can be replicated by referring to the indictor on the knob.

Indications for Use

The Smiths Medical acapella® Choice Blue Vibratory PEP Device is intended for use as a Positive Expiratory Pressure (PEP) device for adults and children (5 years and up). It may also be used simultaneously with nebulized aerosol drug delivery.

Contraindications

Although no absolute contraindications to the use of PEP Therapy have been reported, the following should be carefully evaluated before a decision is made to initiate therapy:

- Inability to tolerate increased work of breathing
- Hemodynamic instability
- Intracranial pressure (ICP) > 20 mm Hg
- Acute sinusitis
- Recent facial, oral or skull surgery or trauma
- Epistaxis
- Esophageal surgery
- Active hemoptysis
- Untreated pneumothorax
- Nausea
- Known or suspected tympanic membrane rupture or another middle ear pathology

Substantial Equivalence

The following table presents the comparison of the acapella devices with a discussion of the differences to follow.

Table 1 Predicate Comparison

Features	Proposed Device acapella® Choice Blue Vibratory PEP Device	Predicate Device acapella® DH
Indications for use	The Smiths Medical acapella® Choice Blue Vibratory PEP Device is intended for use as a Positive Expiratory Pressure (PEP) device for adults and children (5 years and up). It may also be used simultaneously with nebulized aerosol drug delivery.	Intended for use as a Positive Expiratory Pressure (PEP) device. It may also be used simultaneously with nebulized aerosol drug delivery.
Environment of Use	Hospital, clinics, physician offices, home setting	Hospital, clinics, physician offices, home setting
Patient Population	Adults and children (5 years and up) under the supervision of an adult	Adults and children (4 years and up) under the supervision of an adult
Principle of Operation (PEP)	Therapeutic spirometer device that works by assisting the patient to produce oscillatory vibrations in the airways	Therapeutic spirometer device that works by assisting the patient to produce oscillatory vibrations in the airways
Mode of Vibration	Magnetic Rocker assembly	Magnetic Rocker assembly

Table 1 Predicate Comparison		
Features	**Proposed Device acapella® Choice Blue Vibratory PEP Device**	**Predicate Device acapella® DH**
Resistance Dial	Dial for Selection Range: 1 to 5	Dial for Selection Range: 1 to 5
Minimum expiratory flow required	15 L/M	15 L/M
Material / Color / Body Design	Polycarbonate / Blue / Able to be opened for cleaning	Styrene-butadiene / Green / Closed body
Use with a nebulizer	Ability to connect to nebulized aerosol drug delivery system	Ability to connect to nebulized aerosol drug delivery system
Specified Nebulizer	Salter Labs 8900 Series Carefusion Airlife Misty Max 10 Westmed UniHEART	Small Volume Nebulizers
Duration of Use	Single patient, multi-use Up to 6 months use	Single patient, multi-use Up to 6 months use
Cleaning method	Soap / water & disinfecting with Boiling water	Soap / water & disinfecting with Alcohol, or Hydrogen Peroxide or Glutaraldehyde
Accessories	None	Face masks or TheraPrep Pressure Indicator
Components	Mouthpiece, cover and rocker assembly	Mouthpiece and body only; body does not come apart
Biocompatibility ISO 10993-1	Biocompatible based on ISO 10993 • External Communicating (Indirect gas pathway) • Tissue / Bone / Dentin communicating • Duration of Use – prolonged duration based on cumulative exposure (> 24 hours to 30 days) And • Surface Contact • Mucosal membrane • Duration of Use – prolonged duration based on cumulative exposure (> 24 hours to 30 days)	Biocompatible based on ISO 10993
Shelf-life	2 years	2 years

Summary of Technological Characteristics

The technology for delivery PEP therapy is unchanged between the subject and the predicate devices. The subject device shares the same technological characteristics as the 510(k) cleared for the predicate device, acapella® DH (K002768); these characteristics include:

- Provide controllable and variable resistance to the expiratory phase of breathing and therefore creates increased trans-pulmonary pressure within the lung.
- Create vibrations that mimic the oscillatory frequency of cilia. This aids in loosening secretions from the walls of the airways by altering the viscoelastic properties of secretions.
- Contain a flow tube to create a channel for air to pass through and for the vibrations travel back to the user.

- Have an adjustable resistance dial raises and lowers the magnet based on the users' exhalation capacity.
- Contain a mouthpiece that connects the users' mouth to the device.
- Provide the ability to connect a nebulizer in-line that allows the user to inhale the aerosolized drug and then exhale through the PEP device.

The differences between the subject and predicate device are minimal and include differences in the materials of the outer and internal components. The subject device is now able to be opened for cleaning by the user throughout the lifetime of the device, whereas the predicate is a closed system. Smiths Medical has determined these two (2) modifications do not affect the device's intended use, indication for use or alter the device's fundamental scientific technology of Positive Expiratory Pressure therapy.

Summary of Non-Clinical Testing

Non-clinical testing of the components comprising each configuration of the subject *acapella® Choice Blue Vibratory PEP Device* were assessed and tested appropriately to design controls; i.e. design verification, design validations. Testing listed below passed and were verified against their requirements and acceptance criteria:

- Temperature exposure and accelerated aging
- Performance testing (bench) - drop, online therapeutic output, orientation, breakaway pressure, inhalation mode resistance and stutter tests.
- Nebulizer specification verification
- Reprocessing (cleaning and disinfection) verification
- Packaging (transport and distribution) per ASTM D4169
- Biocompatibility per ISO 10993-1
- Biocompatibility per ISO 18562 for gas pathway safety

Additional drug delivery verification testing was conducted for the nebulizer performance with three (3) different aerosol medications (i.e., albuterol sulfate, cromolyn sodium, ipratropium bromide). Specifications were established via a performance test using an eight-stage cascade impactor at a flow rate of 28 L/min equipped with USP induction port throat. Three (3) device samples were tested per each drug. Aerosol was sampled directly from the outlet. The acceptance criteria of the test were that the aerosol performance of any medication, nebulizer, and flow rate would not be statistically different at a confidence level of 95% between the *acapella® Choice Blue Vibratory PEP Device* and acapella® DH as compared to the nebulizer by itself.

Drug delivery performance of *acapella® Choice Blue Vibratory PEP Device* combined with a standard nebulizer configuration was compared to same nebulizer configuration without the *acapella® Choice Blue Vibratory PEP Device.* The delivery of aerosolized drugs with *acapella® Choice Blue Vibratory PEP Device* when connected to a small volume nebulizer was found to be clinically comparable to the performance of the nebulizer alone.

Summary of Differences and Discussion of Substantial Equivalence

The Smiths Medical *acapella® Choice Blue Vibratory PEP Device* is substantially equivalent to the predicate device, acapella® DH, K002786, based on device characteristic comparisons. These characteristics include the similar intended use, same clinical application, same general design, same useful life, same packaging and same principle of operation and similar performance.

The indications for use are similar for patient population, environment and indication. Contraindications are identical to the predicate. The principal of operation is identical to the predicate. The technological characteristic differences are minimal and have been demonstrated to be substantially equivalent through comparative testing to the predicate and do not increase patient risk. Cleaning and disinfection methods are different, and the differences validated. Performance characteristics of the subject and predicate devices, both with and without a nebulizer, have been evaluated and both meet the acceptance criteria and are therefore substantially equivalent.

Substantial Equivalence Conclusion

Smiths Medical concludes the differences between the subject and predicate device do not impact the indications for use, intended use, mechanical and/or fundamental scientific technology of the device, do not raise new or different questions of safety risks imposed on the patient or device use and that the subject device is as safe and effective as the predicate device; therefore, the subject device, *acapella® Choice Blue Vibratory PEP Device*, is considered substantially equivalent to the predicate.