March 27, 2020

ABMRC LLC
Sneha P
QA/RA Lead
239, Fair Child Street, Daniel Island
Charleston, South Carolina 29492

Re: K191912
Trade/Device Name: BiWaze Cough
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: February 21, 2020
Received: February 26, 2020

Dear Sneha P:

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)*
K191912

Device Name
BiWaze Cough

Indications for Use *(Describe)*
This device is designed for use on patients unable to cough or clear secretions effectively due to reduced peak cough exspiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in hospital, institutional setting, or at home. For use on adult patients and pediatric patients 3 years old and up.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter:	ABMRC LLC 239, Fair Child St, Daniel Island, Charleston, South Carolina 29492 www.abmrespiratorycare.com	
Contact:	Chad M Boerst Director ABMRC LLC Email: chadboerst@abmrespiratorycare.com	
Prepared By:	Sneha S P QA/RA Lead ABMRC LLC Email: sneha.sp@abmrespiratorycare.com	
Date Prepared:	March 27, 2020	
Device Proprietary Name:	BiWaze Cough	
Device Common Name:	Secretion Clearance Device	
Classification Regulation Number:	21 CFR 868.5905	
Classification Panel:	Anesthesiology	
Device Classification Code/Name:	NHJ – Non-continuous ventilator (IPPB)	
Classification:	Class II	
Predicate Device:	Philips Respironics Cough Assist T70	K121955
Reference Devices:	Pegaso Cough	K140598
	Lung Assist Vital Cough	K132988

Device Description:

The BiWaze Cough is a device intended for clearing bronchopulmonary secretions. The therapy provided by BiWaze Cough mimics a cough and consists of three phases which mimic a cough; inhale, exhale, and pause phase. The inhale phase is positive airway pressure to expand the lungs. Then the exhale phase is a sudden shift to negative pressure to pull the air out of lungs. Finally, the pause phase provides positive pressure which keeps the airways open in between the therapy cycle.

The Peak Inspiratory Flow can be selected on three different levels: High, Medium, Low.

The device can be operated via a power supply and is also battery operated. Performance is controlled from a touch screen panel in manual or automatic modes. The device is controlled by software algorithms, and error messages are displayed in cases where the normal functioning doesn't occur. Advanced features include inspiratory trigger and oscillations.

Indications for Use:

This device is designed for use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. It may be used either with a facemask, mouthpiece, or an adapter to a patient's endotracheal tube or tracheostomy tube. For use in hospital, institutional setting, or at home. For use on adult patients and pediatric patients 3 years old and up.

Substantial Equivalence Determination:

The table below summarizes the key technical characteristics of BiWaze Cough and the predicate and reference devices listed in the submission:

Technological Characteristic	BiWaze Cough K191912	Philips Respironics CoughAssist T70 K121955	Pegaso Cough K140598	Lung Assist Vital Cough K132988
CFR Classification	868.5905 NHJ	868.5905 NHJ	868.5905 NHJ	868.5905 NHJ
Classification Panel and Class	Anesthesiology Class II	Anesthesiology Class II	Anesthesiology Class II	Anesthesiology Class II
Classification Name	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)
Environments of Use	Hospital, Institutional Setting, homecare	Hospital, Institutional Setting, homecare	Hospital, Institutional Setting, homecare	Hospital, Institutional Setting, homecare
Patient Population	Adult or pediatric patient unable to cough or clear secretions effectively	Adult or pediatric patient unable to cough or clear secretions effectively	Adult or pediatric patient unable to cough or clear secretions effectively	For use on adult or pediatric patients
Delivery Type	Non-Invasive or Invasive	Non-Invasive or Invasive	Non-Invasive or Invasive	-
Modes of Operation	Auto and Manual	Auto and Manual	Auto and Manual	Auto and Manual
Inhalation Pressure	0 to 70 cmH2O	0 to 70 cmH2O	0 to 70 cmH2O	0 to 50 cmH2O
Exhalation Pressure	0 to -70 cmH2O	0 to -70 cmH2O	0 to -70 cmH2O	0 to -50 cmH2O
Inhale Flow	Low, Medium, High	Low, Medium, High	Low, Medium, High	Low, Medium, High
Pause Time	0 to 5 seconds	0 to 5 seconds	0 to 9.9 seconds	0 to 5 seconds
Phases of Therapy Cycle	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause	Insufflation, Exsufflation, Pause
Safety protocols	Dynamic Flow and Pressure control. Sensor malfunction detection. Altitude correction. Pressure and	Dynamic stability Analysis. Flow and Pressure based Oscillation Detection Extreme Flow Rate Control and Response Sensor	Dynamic Flow and Pressure control. Manufacturer Software Calibration eliminates	-

	Flow rate control for smooth pressure output without fluctuations. Valve design ensures spontaneous breathing in event of power failure/standby when patient is connected	Malfunction Stability	all undesired oscillations. Sensor malfunction detection	
Oscillations/Vibrations Frequency	Up to 20 Hz	N/A	Up to 10 Hz	Up to 20 Hz
Therapy Features – Inspiratory Trigger	Yes	Yes (CoughTrak)	Yes (Easy Start/Auto Sync)	-
Remote Data Access	An internal memory stores all data. Encrypted and secure data transfer through USB (2.0) and Wi-Fi (WiLink8 802.11 a/b/g/n + MIMO)	Secure Digital (SD) card	An internal memory stores therapies data. RS232/USB adapter transmits to a PC therapies and technical data.	-
Remote Control	A remote-control accessory (foot pedal) and/or iOS/Android app is provided to initiate manual therapy by means of a remote-control interface	A remote-control accessory (foot pedal) is provided to initiate manual therapy by means of a wired remote-control interface	-	-
Energy Source	100-240 V ac 50/60 Hz	100-240 V ac 50/60 Hz	100/240 V ac 50/60 Hz	100-230 V ac 50-60 Hz
Patient Interfaces	Facemask, Mouthpiece, an adapter to endotracheal tube or tracheostomy tube	Facemask, Mouthpiece, endotracheal tube or tracheostomy tube	Facemask, Mouthpiece, an adapter to endotracheal tube or tracheostomy tube	Facemask, Mouthpiece, an adapter to endotracheal tube or tracheostomy tube

Comparison of Characteristics with respect to Predicate Device:

The BiWaze Cough device has similar features and indications for use when compared to the Predicate Device, Phillips Respironics Cough Assist T70 and the reference devices, Pegaso Cough and Lung Assist Vital Cough. The core capabilities of the BiWaze Cough and its fundamental scientific technology remain unaltered compared to the Phillips Respironics Cough Assist T70. The device modifications discussed do not alter the BiWaze Cough's safety or effectiveness and neither do they change its intended use compared to the predicate.

The table below provides a description of the modifications to the BiWaze Cough device that are subject of this 510(k) submission:

Device Features	Description
User Interface	A new graphic touch display and a new user interface with hierarchical menu system. **SIMILARITIES** The predicate device has similar parameters displayed in the main screen.
Inspiratory Trigger	A feature for patients who can provide spontaneous breathing effort to trigger the Cough sequence, instead of using manual or auto modes therapy. This software feature monitors the device outlet flow and pressure and initiates the insufflation phase of therapy delivery when the flow increases over a set threshold indicative of patient effort. **SIMILARITIES** The Inspiratory Trigger feature is based on the detection of the patient's inspiratory efforts. For this detection a digital flow and pressure sensor is used. The principle is similar to the Respironics CoughAssist T70's CoughTrak and Pegaso Cough's Auto Sync/Easy Start.
Custom Cycle Settings	A feature to customize each breath cycle in terms of pressure, time and oscillations. **REMARKS** This feature is added to provide more flexibility in terms of setting therapy parameters for every individual cycle. This feature is similar to Respironics' T70 Advanced Automatic Mode.
Custom Profiles	The device can save up to 10 custom therapy profiles. **SIMILARITIES** The Custom Profiles feature is provided so that User can select a pre-defined set of therapy parameters. This feature is similar to Respironics CoughAssist T70's Preset feature.
Oscillations	A feature that delivers a pressure oscillation based on frequency and amplitude set points. **SIMILARITIES** The feature is similar to the Percussor feature of the Pegaso Cough device.

Data Management	All therapy data is stored in an internal memory. On request, data can be securely transferred over authenticated link through USB (2.0), Wi-Fi (WiLink8 802.11 b/g/n) **REMARKS** Encrypted data is securely transferred through either USB 2.0, Wi-Fi (WiLink8 802.11 b/g/n) along with additional authentication information.
Wired Remote Control	A remote-control accessory (foot pedal) is provided to initiate manual therapy by means of a wired remote-control interface. **SIMILARITIES** This feature/accessory is similar to that of Respironics CoughAssist T70 device.
Wireless Remote Control	A remote-control accessory (mobile app) is provided to initiate manual therapy by means of a wireless (BLE) remote-control interface.
Power Management	An internal rechargeable battery is included.

Performance Data:

Performance testing was conducted on BiWaze Cough and the device was found substantially equivalent to the predicate device.

Verification activities have been performed to verify that the device modifications did not affect the safety and effectiveness of the subject device. This included bench testing, software unit testing, and code reviews.

The BiWaze Cough device was designed and tested according to the following standards:

- AAMI ANSI ES 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
- IEC 60601-1-11 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
- IEC 62366-1 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and Testing within a Risk Management Process
- ISO 18562-1 Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing within a Risk Management Process

- IEC 62304 Medical Device Software – Software Life Cycle Processes
- ISO 14971 Medical Devices - Application of Risk Management to Medical Devices
- IEEE C63.27:2017 – American National Standard for Evaluation of Wireless Coexistence

Conclusion:

In summary, bench testing and software code reviews have confirmed that the BiWaze Cough device performs substantially equivalent to the cited predicate device. The indications for use, technological characteristics, and principles of operation are similar to the predicate device. The BiWaze Cough device is substantially equivalent to the predicate device.