December 21, 2022

Abmrc LLC
Priyanka Paul
QA/RA Manager
860 Blue Gentian Road Suite 200
Eagan, Minnesota 55121

Re: K213564
Trade/Device Name: BiWaze Clear System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: November 17, 2022
Received: November 18, 2022

Dear Priyanka Paul:

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,

Rachana Visaria -S

Rachana Visaria, 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

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)*
K213564

Device Name
BiWaze Clear System

Indications for Use *(Describe)*
The BiWaze Clear System is indicated for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis and has the ability to provide supplemental oxygen when used with an oxygen supply.

The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 2 years in the acute care setting.
The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 5 years in the home care setting.

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

Submitter	ABMRC LLC 860 Blue Gentian Road, Suite 200, Eagan, MN, 55121 USA www.abmrc.com	
Contact	Priyanka Paul QA/RA Manager ABMRC LLC Email: priyanka.paul@abmrc.com	
Prepared By:	Priyanka Paul QA/RA Manager ABMRC LLC Email: priyanka.paul@abmrc.com	
Date Prepared:	December 21, 2022	
Trade/ Device Name:	BiWaze Clear System	
Device Common Name:	Noncontinuous Ventilator (IPPB)	
Classification Regulation Number:	21 CFR 868.5905	
Classification Panel:	Anesthesiology	
Regulation Name:	NHJ – Non-continuous ventilator (IPPB)	
Classification:	Class II	
Predicate Device:	Volara™ System (Maximus™ System when used as a Volara™ System)	K200988
Reference Devices:	MetaNeb® 4 System	K151689

Device Description:

The BiWaze Clear System assists patients in loosening and mobilizing secretions as well as treating and preventing atelectasis by providing lung expansion and high frequency oscillation therapies. The oscillating lung expansion therapy of the BiWaze Clear System is intended to reduce airway obstructions caused by secretions occupying the lower airways, prevent respiratory tract infections, re-expand the collapsed areas of the lung, thereby enhancing gas exchanges and reducing inflammatory response.

BiWaze Clear provides three respiratory therapies: PEP, OSC, and NEB.

- **Positive Expiratory Pressure (PEP):** During PEP, the system delivers a programmed positive pressure which the patient exhales against to open and expand the patient's airways. The nebulizer can be configured to run during PEP therapy to help move saline throughout the airways.
- **Oscillation (OSC):** During OSC, the system oscillates the airways with pulses of positive pressure to thin secretions and mobilize them from the lower airways to the upper airways so they can be coughed or suctioned out. The nebulizer can be configured to run during OSC therapy to help move saline throughout the airways.
- **Nebulize (NEB):** During NEB, the system powers only the Aerogen Solo vibrating mesh nebulizer. This therapy gives the patient a break from PEP or OSC while the patient receives nebulized saline.

The BiWaze Clear System can be used in conjunction with the various patient interfaces such as facemask, mouthpiece or a trach adapter which connects to a patient's endotracheal or tracheostomy tube. It is intended to deliver therapy to pediatric and adult patients in acute, post-acute, and home care settings.

The BiWaze Clear System provides a closed-circuit therapy with the Dual Lumen Breathing Circuit that prevents aerosolized exhale air from escaping the handset or breathing tube before being filtered by a coaxial bacterial/viral filter.

Indication for Use:

The BiWaze Clear System is indicated for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis and has the ability to provide supplemental oxygen when used with an oxygen supply.

The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 2 years in the acute care setting.
The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 5 years in the home care setting.

Substantial Equivalence Determination:

The BiWaze Clear System has the following similarities to the previously cleared predicate device:

- Indication for use
- Operating principle
- Technology

The BiWaze Clear System has the secretion clearance functionality substantially equivalent to the following devices:

- Hill-Rom Volara™ System (Maximus™ System, when used as a Volara™ System) (K200988) – Predicate Device

Technological Characteristic	BiWaze Clear System (Proposed Device)	Hill-Rom Volara System (Maximus™ System, when used as a Volara™ System) (Predicate Device)	Hill-Rom MetaNab® 4 System (Reference Device)
510(k) Number	**K213564**	**K200988**	**K151689**
CFR Classification	Regulation Number: 21 CFR 868.5905	Regulation Number: 21 CFR 868.5905	Regulation Number: 21 CFR 868.5905
Product Code	Product code: NHJ	Product code: NHJ	Product code: NHJ
Classification Panel and Class	Anaesthesiology Class II	Anaesthesiology Class II	Anaesthesiology Class II
Classification Name	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)	Device, positive pressure breathing, intermittent (IPPB)
Indication For Use	The BiWaze Clear System is indicated for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis and has the ability to provide supplemental oxygen when used with an oxygen supply. The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 2 years in the acute care setting. The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 5 years in the home care setting.	Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with oxygen.	Indicated for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and also has the ability to provide supplemental oxygen when used with compressed oxygen.

Environments of Use	Hospital, Sub-acute facilities, Nursing care Homecare	Hospital, Sub-acute F acilities, Nursing care, Homecare	Hospital sub-acute facilities Nursing care Homecare
Environments of Use	Hospital, Sub-acute facilities, Nursing care Homecare	Hospital, Sub-acute facilities, Nursing care Homecare	Hospital sub-acute facilities Nursing care Homecare
Patient Population	Adult, Child > 2 years old (acute) Adult, Child >5 year (home care)	Adult, Child > 2 years old (acute) Adult, Child > 5 year (home care)	Adult, Child > 2 years old (Acute care) Adult, Child > 5 years old (home care) (K151689)
Therapy Type	Positive Expiratory Pressure (PEP), Oscillation (OSC), NEB	Continuous Positive Expiratory Pressure (CPEP), Continuous High Frequency Oscillation (CHFO), Aerosol	CPEP, CHFO, Aerosol Only
Positive Expiratory Pressure (PEP) / CPEP	Controlled static flow with positive pressure ≤ 30 cmH2O	Controlled static flow with positive pressures < 30 cmH2O	Controlled static flow with positive pressures ≤ 30 cmH2O
Oscillations (OSC) / CHFO	Controlled continuous flow with frequencies up to 300 beats per minute (5 Hz) and peak positive pressures ≤ 70 cmH2O	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressure ≤ 70 cmH2O	Controlled continuous flow with frequencies up to 300 beats per minute and peak positive pressure ≤ 30 cmH2O
NEB / Aerosol	Controlled continuous constant pressure with in- line nebulizer delivering saline.	Controlled continuous constant pressure to in-line nebulizer delivering medicated aerosol only via mouthpiece and face mask. Aerosol may not be delivered when the in-line ventilator adapter is used.	Controlled continuous constant flow to in-line nebulizer delivering medicated aerosol only.
Patient Circuit Configurations	Disposable circuit including handset with connection for in-line nebulizer to deliver saline. .	Disposable circuit referred to as “handset” includes connection for in-line nebulizer. Draw in room air mix with medicated aerosol and gas from controller.	Disposable circuit referred to as “handset” includes connection for in- line nebulizer. Draw in room air mix with medicated aerosol and gas from controller.
Patient Circuit settings	No resistance adjustment feature on patient circuit.	No resistance adjustment feature on patient circuit. All adjustments done at the	Expiratory resistance adjustment ≤ 30 cmH2O

	All adjustments done at the control unit	control unit.	
Patient Interface	Acute care: Mouthpiece, Facemask, Adapter to a patient's endotracheal tube or tracheostomy tube. Home care: Mouthpiece, Facemask, Adapter to a patient's endotracheal tube or tracheostomy tube.	Acute care: Mouthpiece, Facemask, Insert into ventilator, Adapter to a patient's endotracheal tube or tracheostomy tube. Home care: Mouthpiece, Facemask, Insert into ventilator, Adapter to a patient's endotracheal tube or tracheostomy tube.	Mouthpiece Face mask Insert into ventilator circuit
Principle of Operation	Electro-Mechanical device Air or Oxygen	Electro-Mechanical device Air or Oxygen	Pneumatic Air or oxygen
Setting Options	On/Off Frequency selection for OSC mode (Touch Screen Control) Pressure adjustment for OSC mode (Touch Screen Control) Pressure adjustment for PEP mode (Touch Screen Control) Pressure manometer	On/Off Frequency selection for CHFO mode (Touch Screen Control) Pressure adjustment for CHFO mode (Touch Screen Control) Pressure adjustment for CPEP mode (Touch Screen Control) Pressure manometer	On/Off Frequency selection for CHFO mode (control knob) Pressure adjustment for CPEP mode (control knob) Pressure manometer -
Energy Source	100-240 V ac 50/60 Hz	100-240 V ac 50/60 Hz	Pneumatic Source

The table below summarizes the key technical characteristics of BiWaze Clear System and the predicate and reference devices listed in the submission.

Table below provides a description of the modifications to the BiWaze Clear System:

Device Features	Description

User Interface	A new graphic touch display and a new simplified user interface with hierarchical menu system. **SIMILARITIES** The predicate devices have similar parameters displayed in the main screen.
Nebulizer	A vibrating mesh-based nebulizer is used for aerosol or nebulizer therapy in BiWaze clear System. **REMARKS** In the predicate device, a jet pump nebulizer is used for aerosol or nebulizer therapy.
Breathing Circuit	The BiWaze Clear System uses a customized breathing circuit that includes a coaxial breathing tube, coaxial bacterial / viral filter, handset or spacer with a nebulizer port and an optional patient interface (facemask, mouthpiece or flexible trach adapter). **REMARKS** The predicate device uses a breathing circuit that has a single path breathing tube with single path bacterial/viral filter.
Data Management	All therapy data is encrypted and stored in the control unit's internal memory. When connected to a Wi-Fi network, the control unit can send the therapy data to a remote server. **REMARKS** Encrypted data is securely transferred through either USB 2.0 or a Wi-Fi (WiLink8 802.11 a/b/g/n + MIMO) Network.

Substantial Equivalence Discussion

The BiWaze Clear System is viewed as substantially equivalent to the predicate devices for the following reasons:

Indications – The proposed indication for use is identical to the predicate.

Discussion: The indication for use is identical to the predicate device.

Patient Population – The patient populations are identical to the predicate.

Discussion: The patient population is identical to the predicate device.

Environment of Use – The environment of use is identical to the predicate.

Technology – Functionally the performance and therapy mode functions are identical to the predicate device.

Comparison of Characteristics with respect to Predicate Device:
The BiWaze Clear System has similar features and indications for use when compared to the predicate. The core capabilities of BiWaze Clear and its fundamental scientific technology remain unaltered compared to the predicate. The modifications discussed do not alter BiWaze Clear's safety or effectiveness and neither do they change its indication for use compared to the predicate.

Performance Data:
Performance testing – Bench testing was conducted on BiWaze Clear, and it was found to be substantially equivalent to the predicate.

Biocompatibility of Patient Contacting Materials – The materials in the gas and fluid pathway are categorized as externally communicating, tissue contacting with permanent duration (>30 days).

Verification and Validation – This includes non-clinical bench testing and software unit testing as listed below. There have been no animal or clinical studies submitted.

- Comparative Performance Bench Study across all therapy modes (OSC, PEP, Neb) against the predicate
- Comparative Nebulizer Performance Study across all therapy modes and patient interfaces for adult and pediatric flow rates
- Biocompatibility – Main Unit and Dual Lumen Breathing Circuit Components as per ISO 10993-1 and ISO 18562-1
- Software & Firmware verification and validation
- Electrical Safety, EMI /EMC
- Usability
- Cleaning Validation

The BiWaze Clear System was designed and tested according to the following standards:

- IEC 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 18562-1: Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process

- ISO 18562-2: Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
- ISO 18562-3: Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)
- ISO 18562-4: Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachable in condensate
- ISO 10993-1 Biological evaluation of medical devices - 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

Conclusion:

The modifications to the BiWaze Clear System that are the subject of this 510(k) application have been validated through non-clinical testing and determined to be substantially equivalent. In conclusion, bench testing and system verification have confirmed that the performance of the BiWaze Clear System is equivalent to that of the predicate. The indications for use, technological characteristics, and operating principles are comparable the predicate. The BiWaze Clear System is substantially equivalent to the predicate.