April 8, 2024

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

Re: K231728
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: March 9, 2024
Received: March 11, 2024

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 (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,

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)*
K231728

Device Name
BiWaze Clear System

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

The BiWaze Clear System is for use on adult or pediatric patients in acute care (aged 2 years and older) and home care environments (aged 5 years and older).

The BiWaze Clear System may be used with patient interfaces including face mask, mouthpiece, a trach adapter to endotracheal or tracheostomy tube in acute and home care environments. The BiWaze Clear System may be used in-line with a ventilator in acute care environment only.

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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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	
Date Prepared:	April 05, 2024	
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 (Primary):	Volara™ System (Maximus™ System when used as a Volara™ System)	K200988
Reference Device (Existing 510(k) Cleared Device):	BiWaze Clear System	K213564

Indication for Use:

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

The BiWaze Clear System is for use on adult or pediatric patients in acute care (aged 2 years and older) and home care environments (aged 5 years and older).

The BiWaze Clear System may be used with patient interfaces including face mask, mouthpiece, a trach adapter to endotracheal or tracheostomy tube in acute and home care environments. The BiWaze Clear System may be used in-line with a ventilator in acute care environment only.

Device Description and Modification:

The BiWaze Clear System is identical to the BiWaze Clear System cleared under K213564. The present submission extends BiWaze Clear System claims to include use in-line with a ventilator in the acute care environment only.

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 the aerosolized saline solution throughout the airways.
- Oscillation (OSC): During OSC, the system oscillates the airways with pulses of positive pressure to thin secretions and mobilizes 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 the aerosolized saline solution 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 their nebulized aerosolized saline.

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

Substantial Equivalence Determination:

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

- Indication for use
- Operating principle
- Technology

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

- Hill-Rom Volara™ System (Maximus™ System, when used as a Volara™ System) (K200988)– Predicate Device
- ABMRC's FDA 510(k) Cleared Device- BiWaze Clear System (K213564)- Reference Device

Technological Characteristic	BiWaze Clear System (Proposed Device)	Hill-Rom Volara System (Maximus™ System, when used as a Volara™ System) (Predicate Device)	BiWaze Clear System (Reference Devices)
510(k) Number	**K231728**	**K200988**	**K213564**
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	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)
Indication For Use	The BiWaze Clear System is indicated for the loosening and mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and can provide supplemental oxygen when used with an oxygen supply. The BiWaze Clear System is for use on adult or pediatric patients in acute care (aged 2 years and older) and home care environments (aged 5 years and older). The BiWaze Clear System may be used with patient interfaces including face mask, mouthpiece, a trach adapter to endotracheal or tracheostomy tube in	Indicated for mobilization of secretions, lung expansion therapy, treatment and prevention of pulmonary atelectasis, ability to provide supplemental oxygen when used with oxygen.	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.

Technological Characteristic	BiWaze Clear System (Proposed Device)	Hill-Rom Volara System (Maximus™ System, when used as a Volara™ System) (Predicate Device)	BiWaze Clear System (Reference Devices)
510(k) Number	**K231728**	**K200988**	**K213564**
	acute and home care environments. The BiWaze Clear System may be used in-line with a ventilator in acute care environment only.		
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 care) Adult, Child > 5 year (Home care)	Adult, Child > 2 years old (Acute care) Adult, Child > 5 year (Home care)	Adult, Child > 2 years old (Acute care) Adult, Child > 5 years old (Home care)
Therapy Modes	Positive Expiratory Pressure (PEP), Oscillation (OSC), Nebulizer (NEB)	Continuous Positive Expiratory Pressure (CPEP), Continuous High Frequency Oscillation (CHFO), Aerosol	Positive Expiratory Pressure (PEP), Oscillation (OSC), Nebulizer (NEB)
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 (5 Hz) and peak positive pressures, ≤ 70 cmH2O

Technological Characteristic	BiWaze Clear System (Proposed Device)	Hill-Rom Volara System (Maximus™ System, when used as a Volara™ System) (Predicate Device)	BiWaze Clear System (Reference Devices)
510(k) Number	**K231728**	**K200988**	**K213564**
NEB/ Aerosol	Controlled continuous constant pressure with in- line nebulizer delivering saline.	Controlled continuous constant pressure to inline nebulizer delivering medicated aerosol only.	Controlled continuous constant pressure with in-line nebulizer delivering saline.
Principle of Operation	Electro-Mechanical device Air or Oxygen	Electro-Mechanical device Air or Oxygen	Electro-Mechanical device 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 OSC mode (Touch Screen Control) Pressure adjustment for OSC mode (Touch Screen Control) Pressure adjustment for PEP mode (Touch Screen Control) Pressure manometer
Aerosol delivery	Mouthpiece Face Mask Trach Adapter Ventilator Tee Adaptor	Mouthpiece Face Mask Ventilator Tee Adaptor	Mouthpiece Face Mask
Patient Circuit Configurations	Disposable circuit including handset with connection for in-line nebulizer.	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 including handset with connection for in-line nebulizer.

Technological Characteristic	BiWaze Clear System (Proposed Device)	Hill-Rom Volara System (Maximus™ System, when used as a Volara™ System) (Predicate Device)	BiWaze Clear System (Reference Devices)
510(k) Number	**K231728**	**K200988**	**K213564**
Patient Circuit settings	No resistance adjustment feature on patient circuit. All adjustments done at the control unit.	No resistance adjustment feature on patient circuit. Therapy settings are all done at the control unit.	No resistance adjustment feature on patient circuit. All adjustments done at the control unit.
Patient Interface	**Acute care:** Mouthpiece, Facemask, Insert into ventilator, Adapter to a patient's endotracheal tube or tracheostomy tube. **Home care:** Mouthpiece, Facemask, Adapter to a patient's 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.	**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.
SpO2 Connection	Supports connection and displays SpO2 values and heart rate from a SpO2 sensor	Can connect via Bluetooth to Beijing Choice Electronic Technology Co., Ltd. Fingertip Pulse Oximeter, K142888. Only displays the heart rate and SpO2 data	Supports connection and displays SpO2 values and heart rate from a SpO2 sensor
Energy Source	100-240 V ac 50/60 Hz	100-240 V ac 50/60 Hz	100-240 V ac 50/60 Hz

Substantial Equivalence Discussion

The BiWaze Clear System is viewed as substantially equivalent to the predicate devices because:

Indications – The proposed indication for use for mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with compressed oxygen are identical to the predicate.

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

Patient Population – The patient population is identical to the predicate.

Environment of Use – The environment of use is identical to the predicate. However, BiWaze Clear use in-line with ventilator is intended only in the acute care environment.

Technology – Functionally, the performance and therapy mode functions are similar to the predicate device. The proposed modifications are changes to the labelling with supporting data from testing without a change in device technology.

Performance Data: Performance bench testing was conducted on modified BiWaze Clear System in-line with a ventilator, and it was found to be substantially equivalent to the predicate, the Hill Rom's Volara System (K200988).

Biocompatibility– There is no change in design and materials in the gas and fluid pathways are identical to the reference device, BiWaze Clear System (K213564).

Comparison of Characteristics with Respect to the Predicate Device:

The modified BiWaze Clear System has the same features and indications for use when compared to the predicate. The core capabilities of the modified BiWaze Clear System remained unaltered compared to the predicate device. The device modifications discussed do not alter the BiWaze Clear device's safety or effectiveness and neither do they change its indication for use compared to the predicate device.

The modified 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 bench testing and determined to be substantially equivalent to the predicate. Based upon the risk analysis, comparative performance testing, and non-clinical testing, we have demonstrated that the proposed device and predicate device (K200988) are substantially equivalent**.**