August 24, 2026

Abmrc, LLC
℅ Paul Dryden
Consultant
ProMedic Consulting, LLC
131 Bay Pt. Dr. NE
St. Petersburg, Florida 33704

Re: K260604
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: July 23, 2026
Received: July 24, 2026

Dear Paul Dryden:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Binoy J. Mathews -S

Digitally signed by Binoy J. Mathews -S
Date: 2026.08.24 13:43:05 -04'00'

For

James Lee, PhD
Division Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260604

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 system provides three therapies: Positive Expiratory Pressure (PEP), Oscillation (OSC), and delivery of saline via integrated nebulizer (NEB).

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 is compatible with various patient interfaces including face mask, mouthpiece, a trach adapter for connection to an endotracheal or tracheostomy tube in acute and home care settings.

The BiWaze Clear System may be used in-line with a ventilator in acute care environments 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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Date Prepared:	24-Aug-26
Sponsor:	ABMRC LLC 860 Blue Gentian Road Suite 200 Eagan, MN 55121, USA
Sponsor Contact:	Priyanka Paul - Director, Quality & Regulatory Tel - +91-7299334392
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	BiWaze Clear System.
Common/Usual Name:	Noncontinuous ventilator (IPPB)
Classification:	NHJ, 868.5905
Predicate Device:	BiWaze Clear System, ABMRC LLC, K231728
Common/Usual Name:	Noncontinuous ventilator (IPPB)
Classification:	NHJ, 868.5905

Device Description:
The proposed device is similar to the predicate cleared under K231728 except for the addition of Bluetooth connectivity and the addition of an FDA-cleared filter (K192713).

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 delivers three therapies: Positive Expiratory Pressure (PEP), Oscillation (OSC), and nebulizer (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 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 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 their 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, or in-line with a ventilator. 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 exhalation of air from escaping the handset or breathing tube before being filtered by a coaxial bacterial/viral filter.

The BiWaze Clear System consists of a main controller and single patient, multi-use breathing circuit which includes various patient interface options.

- Mouthpiece
- Face Mask
- Trach Adapter
- Two Step Adaptor

Principle of Operation
The BiWaze Clear System delivers positive expiratory pressure for lung expansion therapy and produces high-frequency oscillations up to 300 beats per minute (5 Hz) and peak positive pressures ≤ 70 cmH_2O to break up mucus and move it up the mucociliary escalator.

The device can deliver nebulized saline during oscillation and positive expiratory pressure phases. The nebulizer can also be used independently to deliver aerosol saline.

Indications 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 system provides three therapies: Positive Expiratory Pressure (PEP), Oscillation (OSC), and delivery of saline via integrated nebulizer (NEB).

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 is compatible with various patient interfaces including face mask, mouthpiece, a trach adapter for connection to an endotracheal or tracheostomy tube in acute and home care settings.

The BiWaze Clear System may be used in-line with a ventilator in acute care environments only.

Patient Population:
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).

Environments of use:
The BiWaze Clear System is used in acute care (aged 2 years and older) and home care environments (aged 5 years and older).

Substantial Equivalence Discussion

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

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

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.

Performance Data: Performance bench testing was conducted related to the addition of a filter to the breathing circuit. The comparative testing to the predicate was found to be substantially equivalent.

Biocompatibility: The design and materials in the gas and fluid pathways are identical to the predicate, BiWaze Clear System (K231728).

Discussion of Differences

The difference between the proposed device and the predicate are:

- Enabling Bluetooth connectivity
- Addition of an FDA-cleared filter to the breathing circuit

These changes do not raise different questions of safety and effectiveness compared to the predicate and can be considered substantially equivalent.

Nonclinical Testing Summary

Based upon the modification the following nonclinical testing performed as part of demonstrating substantial equivalence to the predicate.

- Software verification and validation was performed
- Cybersecurity
- Wireless co-existence testing
- IEC 60601-1
- IEC 60601-1-2
- Testing was conducted to assess device performance with the addition of a filter to the breathing circuit. The comparative testing was performed with and without the filter. Testing with the filter was found to be substantially equivalent to the predicate. Testing was performed with PAP and OSC therapies and included various, clinically relevant, pressures and frequencies (low, medium, and high) with a range of resistance and compliance settings to simulate patient condition and age (adult vs. pediatric).

In all cases the modified device met it performance specifications and can be considered substantially equivalent to the predicate.

Table - Comparison of Subject vs. Predicate

	Subject Device BiWaze Clear	Predicate BiWaze Clear – K231728	Comparison
Product Code	NJH - Noncontinuous ventilator (IPPB)	NJH - Noncontinuous ventilator (IPPB)	Identical
CFR	868.5905	868.5905	Identical
Indications 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 system provides three therapies: Positive Expiratory Pressure (PEP), Oscillation (OSC), and delivery of saline via integrated nebulizer (NEB). 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 is compatible with various patient interfaces including face mask, mouthpiece, a trach adapter for connection to an endotracheal or tracheostomy tube in acute and home care settings. The BiWaze Clear System may be used in-line with a ventilator in acute care environments only.	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.	Similar Language updated for clarity and added details of nebulizer use with saline previously cleared.
Environment of Use	Hospital, Sub-acute facilities, Nursing care Homecare	Hospital, Sub-acute facilities, Nursing care Homecare	Identical
Patient Population	Adult, Child > 2 years old (Acute care) Adult, Child > 5 years (Home care)	Adult, Child > 2 years old (Acute care) Adult, Child > 5 years (Home care)	Identical
Fundamental technology	Electro-Mechanical device Air or Oxygen	Electro-Mechanical device Air or Oxygen	Identical
Therapy Modes	Positive Expiratory Pressure (PEP), Oscillation (OSC), Nebulizer (NEB)	Positive Expiratory Pressure (PEP), Oscillation (OSC), Nebulizer (NEB)	Identical

	Subject Device BiWaze Clear	Predicate BiWaze Clear – K231728	Comparison
Positive Expiratory Pressure (PEP) / CPEP	Controlled static flow with positive pressure ≤ 30 cmH2O	Controlled static flow with positive pressure ≤ 30 cmH2O	Identical
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 (5 Hz) and peak positive pressures ≤ 70 cmH2O	Identical
NEB / Aerosol	Controlled continuous constant pressure with in- line nebulizer delivering saline	Controlled continuous constant pressure with in- line nebulizer delivering saline	Identical
Aerosol delivery	Mouthpiece, Face Mask Trach Adapter, Two Step Adaptor	Mouthpiece, Face Mask Trach Adapter, Two Step Adaptor	Identical
Nebulizer	Aerogen® Solo	Aerogen® Solo	Identical
Patient Circuit	Disposable circuit including handset with connection for in-line nebulizer.	Disposable circuit including handset with connection for in-line nebulizer.	Identical
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, Adapter to a patient's tracheostomy tube.	Identical
SpO2 Sensor	Supports connection and displays SpO2 values and heart rate from a SpO2 sensor	Supports connection and displays SpO2 values and heart rate from a SpO2 sensor	Identical
Settings	On/Off Touch Screen Frequency selection Pressure adjustment for OSC Pressure adjustment for PEP mode Pressure manometer	On/Off Touch Screen Frequency selection Pressure adjustment for OSC Pressure adjustment for PEP mode Pressure manometer	Identical
Wireless Connectivity	Bluetooth and Wi-Fi	Wi-Fi	Similar Testing demonstrated subject device was as safe and effective with enabled Bluetooth.
Biocompatibility	ISO 10993-1 ISO 18562-1	ISO 10993-1 ISO 18562-1	Identical

Substantial Equivalence Conclusion

The BiWaze Clear device has been determined to be substantially equivalent to BiWaze Clear, K231728, based upon the proposed modifications and that the subject device's performance is unchanged. The intended use, indication for use, technological characteristics and principles of operation are similar to the predicate device. It can be concluded that the proposed device is substantially equivalent to the predicate.