May 16, 2025

Breas Medical AB
Ivan Liljegren
Senior Vice President, Global QA/RA
Foretagsvagen 1
Molnlycke, 435 33
Sweden

Re: K242438
Trade/Device Name: Clearo
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: NHJ
Dated: August 16, 2024
Received: August 16, 2024

Dear Ivan Liljegren:

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.

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,

Rachana Visaria -S

Rachana Visaria, PhD.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
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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)*
K242438

Device Name
Clearo

Indications for Use *(Describe)*
Clearo is indicated for use on adult or pediatric patients unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. The device is intended to be used in the hospital, institutional environment or in the home.

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.

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510(k) SUMMARY

Breas Medical Clearo

510(k) #: K242438

Date Prepared: May 16, 2025

Contact Details

Applicant Name:	Breas Medical AB
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Device Name

Device Trade Name	Clearo
Common Name	Device, Positive Pressure Breathing, Intermittent (IPPB)
Classification Name	Non-continuous ventilator
Regulation Number	21 C.F.R. §868.5905 Class II
Product Code(s)	NHJ

Primary Predicate Device(s)

Respironics CoughAssist T70 Device cleared in K121955, Product Code NHJ

Reference Device(s)

ABMRC LLC BiWaze Cough cleared in K191912, Product Code NHJ

Device Description Summary

The Breas Medical Clearo is an airway clearance device that provides Mechanical Insufflation-Exsufflation (MI-E) therapy. Clearo is indicated for use on adult or pediatric patients who are unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. The device is intended to be used in the hospital, institutional environment or in the home.

The Clearo device is not intended to be used in line with a ventilator.

Clearo must be prescribed by a licensed physician and must be used only as directed by a physician or healthcare provider.

Clearo must be used with a single-limb patient circuits fitted an anti-bacterial filter.

Clearo functions by delivering ambient air at a defined positive pressure to the patient's airways (insufflation), followed by a rapid shift to negative pressure (exsufflation). This quick transition—known as "time through zero" – creates a high expiratory flow that stimulates or simulates a natural cough.

Optional oscillatory vibrations may further aid in loosening and mobilizing secretions. The continued rapid transition to negative pressure helps generate sufficient expiratory flow from the central airways, supporting the clearance of respiratory secretions.

Clearo achieves its intended use through a blower, which compresses air, a solenoid- controlled valve to manage air flow and pressure, and microcontroller electronics to control and monitor the operation. Clearo is powered from either a mains source or an internal battery.

Clearo includes the following device modes to accommodate both clinical and patient use:

- Unlocked (Clinical) Mode: Provides full access to all treatment settings and mode configurations, intended for use by healthcare professionals. Clinicians can enable specific modes for patient use and customize treatment protocols.
- Locked (Patient) Mode: Restricts access to pre-selected modes as set by the clinician. Patients cannot modify treatment parameters but may view compliance data and alarm history.

Clearo provides the following Treatment Modes:

- Manual Mode: The user controls the cycling between insufflation and exsufflation via a manual switch. This mode supports "Insufflation Rise" to control pressure ramp-up. Sessions can be recorded and stored for repeated use using the Treat-Repeat feature.
- Basic Auto Mode: Provides repeated, automatic cycling of insufflation, pause, and exsufflation, with configurable recruitment breaths, pause intervals, rise time, and optional patient-triggered breaths. Optional Stepped Insufflation Breaths gradually increases insufflation pressure across breaths for comfort.
- Program Auto Mode: Similar to Basic Auto but with a customizable, repeatable sequence of multiple insufflations followed by one exsufflation. Includes all features of Basic Auto Mode.

Intended Use/ Indications for Use

Clearo is indicated for use on adult or pediatric patients unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. The device is intended to be used in the hospital, institutional environment or in the home.

Technological Characteristics Comparison

The table below summarizes the key technical characteristics between the Clearo to those of the predicate device listed in the submission

Technical Characteristic	Breas Medical AB. Clearo (Subject device)	Respironics, Inc. CoughAssist T70 (Primary predicate device – K121955)	Discussion of Differences
Indications for Use	Clearo is indicated for use on adult or pediatric patients unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. The device is intended to be used in the hospital, institutional environment or in the home.	The Philips Respironics CoughAssist T70 is intended for use on adult or pediatric patients unable to cough or clear secretions effectively. It may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. The device is intended to be used in the hospital, institutional environment or in the home.	Same
Delivery Type	Non-invasive or invasive	Non-invasive or invasive	Same
Patient Population	Pediatric through adult patients	Pediatric through adult patients	Same
Use Environment	Home, institutions, hospital.	Home, institutions, hospital	Same
Patient Circuit Types	Patient circuit with bacterial Filter	Patient circuit, including bacteria filter	Same
Patient Interfaces	Facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube	Facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube	Same
Gas Delivery System and Air Source	Blower and valve, Ambient air	Blower and valve, Ambient air	Same
Power source	Mains Non-detachable lithium-ion internal battery	Mains Detachable lithium-ion internal battery	Similar
SpO2 and Pulse Rate Monitoring	Ability to connect optional SpO2 sensor accessories	Ability to connect SpO2 sensors with optional Oximetry Interface Kit accessory	Similar
Cough Modes	Manual Mode Basic Auto Mode Program Auto Mode	Manual Mode Auto Mode Advanced Auto Mode	Similar

Pause Time	0 to 5.0 sec between Insufflation Breaths Only available in Basic Auto Mode or Program Auto Mode	0 to 5.0 sec between Insufflation Breaths. Only available in Auto Mode or Advanced Auto Mode.	Similar
Insufflation Rise	Settable between 1 to 10 (fast to slow).	Referred to as Inhale Flow, settable from Low, Medium or High.	Similar
Insufflation Trigger	Settable to Off, 1-10 representing levels of triggering Not available in Manual Mode	Referred to as Cough-Trak. Not settable for triggering sensitivity Not available in Manual Mode	Similar
Insufflation Pressure	3 to 70 cmH2O	0 to 70 cmH2O	Similar
Exsufflation Pressure	-3 to -70 cmH2O	0 to -70 cmH2O	Similar
Inhale Time	0.5 to 5.0 sec	0 to 5 sec	Similar
Exhale Time	0.5 to 5.0 sec	0 to 5.0 sec	Similar
Physiological Alarms	None	None	Same
Technical Alarms	High Pressure Alarm, Power Source Changed Alarm, Power Fail Alarm, Pressure Measurement Fault Alarm, Pressure Sensor Fault Alarm, Battery Exhausted Alarm, SpO2 Sensor Disconnected Alarm, Low Battery Power Alarm	None	. The presence of alarms does not raise new questions of safety and effectiveness.

The table below summarizes the key technical characteristics between the Clearo to those of the reference device listed in the submission

Technical Characteristic	**Breas Medical AB. Clearo (Subject device)**	**ABMRC LLC BiWaze Cough(reference device)**	**Discussion of Differences**
510(k) Number	K242438	K191912	-
Oscillations Frequency	1 to 20 Hz	5 to 20 Hz	Similar

Similarities between the subject and predicate devices

Similar to the Respironics CoughAssist T70, the Breas Medical Clearo is a microprocessor- controlled, turbine-based mechanical insufflation-exsufflation device indicated for use on adult or pediatric patients unable to cough or clear secretions effectively. Both devices may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. Both devices are intended to be used in the hospital, institutional environment or in the home.

Clearo also include oscillations as a feature of its mechanical insufflation-exsufflation therapy, wherein the device delivers an oscillation on the pressure signal based on frequency and amplitude set points. The addition of oscillations on the pressure signal of Clearo is a feature already cleared in AMBRC LLC BiWaze Cough device (reference device K191912). The use of Biwaze Cough as a reference device supports the substantial equivalence of the oscillation therapy feature in MI-E. The maximum amplitude of oscillation is 10cmH2O which is within the declared amplitude of oscillation delivered by the reference device.

Differences between the subject and predicate devices

Unlike the Respironics CoughAssist T70 predicate device, Clearo has technical alarms including High Pressure Alarm, Power Source Changed Alarm, Power Fail Alarm, Pressure Measurement Fault Alarm, Pressure Sensor Fault Alarm, Battery Exhausted Alarm, SpO2 Sensor Disconnected Alarm, Low Battery Power Alarm. These alarms are non-physiological alarms and are not new technology to active medical devices. The addition of alarms which are compliant with IEC 60601-1-8:2020 do not raise additional questions of safety and effectiveness since the addition of these alarms to the device reduces the risk of treatment not being delivered with Clearo.

Non-clinical and/or Clinical Tests Summary and Conclusions

Breas Medical's Clearo mechanical insufflation-exsufflation device was subjected to performance testing which verified conformance with all requirements specifications and applicable standards, and which included comparative testing with the Respironics CoughAssist T70 predicate device.
Performance testing included testing to the standards and procedures listed below:

Performance Testing to Standards:

- Electrical Safety: IEC 60601-1:2020 Edition 3.2 Consolidated Version, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- Electromagnetic compatibility: IEC 60601-1-2:2020 Edition 4.1 Consolidated Version, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbances-Requirements and tests.
- Usability: IEC 60601-1-6:2020 Edition 3.2 Consolidated Version, Medical electrical equipment- Part 1-6: General requirements for basic safety and essential

performance-Collateral standard: Usability

- Alarms systems: IEC 60601-1-8:2020 Edition 2.2 Consolidated Version, Medical electrical equipment-Part 1-8: General requirements for basic safety and essential performance-Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- Medical equipment used in home healthcare environment: HA60601-1-11:2015+A1:2021, Medical electrical equipment-Part 1-11: General requirements for basic safety and essential performance-Collateral standard: Requirements for medical electrical equipment systems used in the home healthcare environment
- Pulse oximeter equipment: ISO 80601-2-61:2017 Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

Biocompatibility:

- Tissue Contacting Materials:

Component/Part	Type of Contact	Duration of Contact
Exterior Surface of Clearo Main Unit and Accessories	Direct, Surface Device, Intact skin	>30 days
Clearo airpath	Indirect, External Communicating Device: Tissue/Bone/Dentin	>30 days
Clearo Patient Circuit and Bacterial Filter	Indirect, External Communicating Device: Tissue/Bone/Dentin	>30 days

- Biological evaluation was conducted according to FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on September 8, 2023.
- Principles of ISO 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process is applied in determining the biocompatibility plan for Clearo.
- The entire gas pathway including the Clearo device, MI-E Circuit and Bacterial Filter accessories have been evaluated for particulate matter per ISO 18562-2:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter. Particulate matter emissions using clinically-relevant flow rates and total flow volumes yielded acceptable particulate matter emissions level for all patient populations indicated for the device.
- Additionally, the entire gas pathway including Clearo device, MI-E Circuit and

Bacterial Filter accessories have been evaluated for volatile organic compounds per

- ISO 18562-3:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3, Tests for emissions of volatile organic compounds. VOC emissions using clinically-relevant flow rates and total flow volumes yielded acceptable particulate matter emissions level for all patient populations indicated for the device.

Human factors:

- Human factors validation testing was conducted according to the FDA Guidance: Applying Human Factors and Usability Engineering to Medical Devices. Issued on: February 3, 2016.

Cleaning:

- Cleaning Validation was performed according to FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Issued on: March 17, 2015, updated on June 9, 2017.

Software:

- Software information included Verification and Validation testing per FDA Guidance, "Content of Premarket Submissions for Device Software Functions Guidance.
- System-level validation against user requirement specifications were performed according to plans and protocols and have met all acceptance criteria.

Cybersecurity:

- Security Risk Management is employed in conformance to FDA's Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. This is in parallel to safety risk management per ISO 14971.

Comparative Performance Testing:

- Waveform comparison testing was performed against the Respironics CoughAssist T70. Results confirm that the Clearo and the CoughAssist T70 predicate have comparable waveforms across the various modes for mechanical insufflation-exsufflation therapy.

Other Testing:

Clearo performance testing was conducted, including:

- Pressure at 10 cmH2O intervals from across the pressure range (70 cmH2O, -70 cmH2O) in all modes. In addition, pressure is tested at 3 cmH2O and -3 cmH2O.
- Flow to ensure a max flow of at least 300 l/min.
- Timing parameters Ti, Te and Pause across their full ranges.

- Oscillation performance at all combinations of frequency range (1 Hz to 20 Hz) and amplitude range (1 cmH2O to 10 cmH2O).

Conclusions

The comparison of features, performance, and intended use demonstrates that the subject device, Clearo, has the same intended use, similar technological characteristics, and similar performance characteristics as the predicate device, Respironics CoughAssist T70 (K121955). The differences do not raise different questions of safety or effectiveness than the predicate device. Therefore, the subject device Clearo is substantially equivalent to the predicate Respironics CoughAssist T70.