May 20, 2025

Breas Medical AB
Ivan Liljegren
Senior Vice President, Global QA/RA
Foretagsvagen 1
Molnlycke, 45333
Sweden

Re: K242485
Trade/Device Name: EveryWare
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: MOD, MNS, MNT, NOU, CBK
Dated: April 14, 2025
Received: April 16, 2025

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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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.

Submission Number *(if known)*

K242485

Device Name

EveryWare

Indications for Use *(Describe)*

EveryWare is indicated to support clinicians by managing data of patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. EveryWare provides remote patient data collection & viewing and is intended to be used by healthcare representatives in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings. EveryWare is intended to be used in hospital, institutional, provider, and home care settings.

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.

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510(k) SUMMARY – K242485

Breas Medical
EveryWare

510(k) Owner
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Date Prepared:
May 15, 2025

Trade Names of Device
EveryWare

Common or Usual Name
(Accessory to) Continuous Ventilator

Classification Name
Regulation: 21 C.F.R. §868.5895 Continuous Ventilator, Class II

Primary Predicate Device(s)
ResMed Ltd. AirView cleared in K151901

Secondary Predicate Device(s)
Respironics Inc. Care Orchestrator (Sapphire) cleared in K152356

Device Description

EveryWare is a platform that gathers treatment information from Breas respiratory devices in a secure cloud-based system. The data from ventilator is sent over a cellular modem through a cellular network to a cloud-hosted secure data storage system. The authenticated users access this cloud hosted system from a browser in their computer.

EveryWare is indicated to support clinicians by managing data of patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. EveryWare provides remote patient data collection & viewing and is intended to be used by

healthcare representatives in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings. EveryWare is intended to be used in hospital, institutional, provider, and home care settings.EveryWare securely connects compatible medical devices located at the point of patient care to the cloud, and provides authorized healthcare representatives the means to manage patient and device information and settings. EveryWare does NOT alter the intended use of connected medical devices or provide functions to automate diagnosis or therapy.

Indications for Use

EveryWare is indicated to support clinicians by managing data of patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. EveryWare provides remote patient data collection & viewing and is intended to be used by healthcare representatives in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings. EveryWare is intended to be used in hospital, institutional, provider, and home care settings.

Indications for Use Comparison

The Indications for Use for EveryWare fall fully within the indications for use of the primary predicate device and the secondary predicate device.

Technological Characteristics Compared to Predicate

Similar to ResMed AirView and Respironics Care Orchestrator, EveryWare is a medical device data management system comprised of a web-based graphical user interface and a component for wireless connection to the compatible therapy devices. Compatible therapy devices for EveryWare only include devices belonging to the MNS, MNT, NOU and CBK product codes, whereas AirView and Care Orchestrator are also compatible with therapy devices that are in BZD product code.

Aside from supporting clinicians to manage data on patients who are prescribed with compatible therapy devices in accordance with the intended use of these therapy devices, both EveryWare, AirView and Care Orchestrator allow settings in the compatible non-life support therapy devices to be changed remotely. EveryWare does not allow ventilation modes to be changed remotely.

The wireless connection of the therapy devices to AirView is through a cellular modem that can either be embedded in the therapy device, or provided by means of a separate connectivity module. The physical component for wireless connection of the therapy devices to Care Orchestrator is embedded within the therapy device itself, and can either be a bluetooth or cellular modem wireless connection. EveryWare uses a cellular modem called iLink that needs to be connected via USB to the therapy device.

The following table presents similarities and differences with the predicates. There are no additional technological features that the EveryWare has which are not already cleared in AirView and/or Care Orchestrator.

Characteristic	Breas Medical AB, EveryWare (subject device)	ResMed Ltd. AirView (K151901)	Respironics, Inc Care Orchestrator (K152356)	Discussion of Differences
Intended Use	EveryWare is indicated to support clinicians by managing data of patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. EveryWare provides remote patient data collection & viewing and is intended to be used by healthcare representatives in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings.	AirView is a web based solution for healthcare specialists intended to assist in the diagnosis of sleep disordered breathing in adult patients through analysis of data recorded by an AirView compatible home sleep device. Transfer and display machine and therapeutic information that has been transmitted remotely from the patient's therapy device. It is intended to support the standard follow - up care of patients that have been prescribed a compatible ResMed therapy device. AirView also provides remote settings capabilities for non-life support devices only.	Sapphire [Care Orchestrator] is intended to support clinicians by tracking data on patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. Sapphire [Care Orchestrator] provides remote patient data collection & viewing and is intended to be used by healthcare representatives (e.g.,Physicians, Clinicians, Durable Medical Equipment providers) in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings.	Similar
Environment of Use	EveryWare is intended to be used in hospital, institutional provider, and home care settings.	Healthcare professional's computer; Clinical users, home care providers (HCPs) and other healthcare specialists.	Sapphire [Care Orchestrator] is intended to be used in hospital, institutional provider, and home care settings.	Similar

Characteristic	Breas Medical AB, EveryWare (subject device)	ResMed Ltd. AirView (K151901)	Respironics, Inc Care Orchestrator (K152356)	Discussion of Differences
User Population	EveryWare is intended to be used by the following 3 user groups: - Prescribing physicians, nurses, respiratory therapists, physiotherapists and technicians - Durable Medical Equipment (DME)/Homecare providers (HCPs)/Home Medical Equipment providers (HMPs) including managers and administrators	Clinical users, home care providers (HCPs) and other healthcare specialists	Healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers) and patients	Similar
Application Type	Web-based application	Web-based application	Web-based application	Same
Product Codes Supported by Remote Prescription Change Functionality	MNS MNT	MNS BZD	MNS MNT BZD	Similar to K152356 with respect to compatible ventilators supported.
Product Codes NOT SUPPORTED by Remote Prescription Change Functionality	NOU CBK	CBK MNR	NOU CBK	Similar
Data Transfer Technology	Wireless (cellular modem) SD Card File upload/Internet	Wireless (cellular modem) SD Card File upload/Internet USB Stick/Internet	Wireless (Bluetooth or cellular modem) SD Card/Internet	Similar

Characteristic	Breas Medical AB, EveryWare (subject device)	ResMed Ltd. AirView (K151901)	Respironics, Inc Care Orchestrator (K152356)	Discussion of Differences
Functionality	Centralized database Patient Management Display therapy data Generate reports Settings management for non-life supporting devices	Centralized database Patient Management Display therapy data Generate reports Settings management for non-life supporting devices	Centralized database Patient Management Display therapy data Generate reports Settings management for non-life supporting devices	Same
Therapy Settings Management (for non-life support devices), including:	Performance Settings Prescription	Performance Settings Prescription Mode	Performance Settings Prescription Mode	Similar. The absence of Therapy Mode Change does not raise new questions of safety and effectiveness.
- Therapy Mode Change	No	Yes	Yes	Different The absence of Therapy Mode Change does not raise new questions of safety and effectiveness.
- Target Volume Setting	Yes	Yes	Yes	Same
- IPAP & EPAP Settings	Yes	Yes	Yes	Same
- Breath Rate and Insp. Time Setting	Yes	Yes	Yes	Same
- Rise Time & Ramp Pressure Setting	Yes	Yes	Yes	Same
- Humidifier Setting	No	Yes	Yes	Different The absence of Humidifier Setting does not raise new questions of safety and effectiveness.

Characteristic	Breas Medical AB, EveryWare (subject device)	ResMed Ltd. AirView (K151901)	Respironics, Inc Care Orchestrator (K152356)	Discussion of Differences
- High Minute Volume , Disconnection & Apnea alarm	Yes	No	Yes	Similar to K152356
- Mask Resistance & Mask Resistance Lock	No	No	Yes	Similar to K151901.
- View Optional Screen	No	No	Yes	Similar to K151901.
- Tubing Type & Tubing Type Lock	No	No	Yes	Similar to K151901.
- Automated Airway Management	No	No	Yes	Similar to K151901.
Reports	Detailed report (includes compliance information)	Detailed report (includes compliance information)	Detailed report (includes compliance information)	Same
Labeling	Online help file within the application	Online help file within the application	Online help file within the application	Same
Viewing of data	Interactive viewing of data based on user selected date range	Interactive viewing of data based on user selected date range	Interactive viewing of data based on user selected date range	Same

Non-clinical Testing

EveryWare was designed and subjected to performance testing in accordance with all applicable requirements, specifications, guidance documents and recognized consensus standards:

- Content of Premarket Submissions for Device Software Functions. Guidance for Industry and Food and Drug Administration Staff (June 14, 2023)
- Off-the-Shelf Software Use in Medical Devices. Guidance for Industry and Food and Drug Administration Staff (August 11, 2023)
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission. Guidance for Industry and Food and Drug Administration Staff (September 27, 2023)

- Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff (February 3, 2016)
- IEC 60601-1 Edition 3.2:2020
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1:2020
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 62304 Edition 1.1 2015
  Medical device software - Software life cycle processes

EveryWare, by itself, is not intended for diagnosis and treatment of disease or medical condition. EveryWare does not change the performance specification of the connected therapeutic devices. Therefore, no further performance data is required to demonstrate substantial equivalence.

Conclusion

EveryWare is substantially equivalent to the AirView and Care Orchestrator (Sapphire), as the devices share a common intended use and technological characteristics as demonstrated through performance testing.