July 6, 2023

Maquet Critical Care AB
% Barb Smith
Sr. Regulatory Affairs Specialist
Getinge
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K230173
Trade/Device Name: Servo-air Lite Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNT
Dated: June 5, 2023
Received: June 6, 2023

Dear Barb Smith:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230173

Device Name
Servo-air Lite Ventilator System

Indications for Use *(Describe)*
Servo-air Lite Ventilator System is an assist ventilator indicated for augmenting ventilation in spontaneously breathing patients who require mechanical ventilation due to respiratory failure or chronic respiratory insufficiency. It offers non-invasive ventilation, invasive ventilation, and respiratory monitoring.

Servo-air Lite Ventilator System is intended for adult and pediatric patients weighing 15 kg and above.

Servo-air Lite Ventilator System is to be used only by healthcare professionals.

Servo-air Lite Ventilator System is to be used only in professional health care facilities and for transport within these facilities. It is not intended for transport between health care facilities.

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

as required by section 21 CFR 807.92

Device owner	Maquet Critical Care AB Röntgenvägen 2 SE-171 54 Solna, Sweden Tel: (011) 46 10 335 7300
Contact Persons for this submission:	Mrs Elise Brun Regulatory Affairs Manager Phone: direct: (011) 46 10 335 7300 Email: elise.brun@getinge.com
Application Correspondent:	Mrs Barb Smith Sr. Regulatory Affairs Specialist Getinge 45 Barbour Pond Drive Wayne, NJ 07470 Email: barb.smith@getinge.com Phone: 585-370-6101
	Date prepared: June 2, 2023

Trade Name :	Model:	Model no:
Servo-air Lite Ventilator System	Servo-air Lite	68 93 200

Device Classification

Common Name	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use
Classification Number	MNT
Class	II
Regulation Number	21 CFR 868.5895
510(k) Number	K230173

Predicate Device Identification

Respironics V60	K102985

Reference Device Identification

Maquet Servo-air Ventilator System	K192604
Maquet Servo-u Ventilator System	K201874
Nihon Kohden NKV-330 Ventilator	K213521
Fisher&Paykel Airvo 2 Humidifier	K131895

Indications for Use

Servo-air Lite Ventilator System is an assist ventilator indicated for augmenting ventilation in spontaneously breathing patients who require mechanical ventilation due to respiratory failure or chronic respiratory insufficiency. It offers non-invasive ventilation, invasive ventilation, and respiratory monitoring.

Servo-air Lite Ventilator System is intended for adult and pediatric patients weighing 15 kg and above.

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Device Description
The Servo-air Lite Ventilator System consists of a Patient Unit where gases are mixed and administered, and a User Interface where the settings are made and ventilation is monitored.

The Servo-air Lite Ventilator System is based on the cleared reference device Servo-air Ventilator System (K192604), with additions based on reference device Servo-u Ventilator System (K201874).

The ventilator delivers controlled or supported breaths to the patient, with constant pressure, using a set oxygen concentration. The ventilator can also deliver High Flow therapy with a constant flow.

Servo-air Lite contains a dedicated controller circuit for the Aerogen Solo nebulizer (included as standard).

Accessories for CO2 monitoring are available as options.

The Servo-air Lite Ventilator System will produce visual and audible alarms if any parameter varies beyond pre-set or default limits and log alarm recordings.

The system contains provisions for battery modules to supply the system in the case of mains power failure or during intra-hospital transport.

Comparison to Predicate Device

Comparison of Intended Use/Indications Use
The Indications for Use for the proposed Servo-air Lite Ventilator System are equivalent to the Indications for Use for the predicate device Respironics V60 K102985.

MAQUET bases this 510(k) notification on that the Servo-air Lite Ventilator System fulfils the appropriate product standards and is substantially equivalent with the already cleared predicate Respironics V60 (K102985).

Comparison of Technology Characteristics
The technology is similar between predicate device Respironics V60 (K102985) and subject device Servo-air Lite.

Product codes
The predicate device Respironics V60 (K102985) has the same product code (MNT) as the subject device Servo-air Lite.

Additions
The subject device also includes:

- Nebulizer from Aerogen
- Dual limb VBS
- High Flow Therapy
- Hot swappable batteries
- CO_2 monitoring (Optional)

Non-clinical Testing and Performance

Maquet Critical Care has conducted risk analysis and performed necessary verification and validation activities to demonstrate that the design output of the modified devices meet the design input requirements:

Software

- Code review
- Static code analysis
- Unit tests
- Integration tests

Performance

- System testing
- Regression
- Free User testing
- Waveform testing

Biocompatibility

- Volatile Organic Compounds

- Particulate Testing
- Leachable testing

Human Factors Validation Testing

The following product standards are included in the verification:

- ANSI/AAMI ES 60601-1:2005 + A1:2012, Medical electrical equipment Part 1: General requirements for basic safety and essential performance, Recognition Number 19-4
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and Test, Recognition Number 19-8
- IEC 60601-1-8:2006 + A1:2012, 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, Recognition Number 5-76
- ISO 80601-2-12:2020, Medical electrical equipment -- Part 2-1: Particular Requirements For The Safety Of Lung Ventilators - Critical Care Ventilators, Recognition Number 1-98
- ISO 80601-2-55:2018, Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors, Recognition Number 1-140
- EN13544-1:2007, this standard is not recognized by FDA

Biocompatibility evaluation of the Servo-air Lite is in accordance with AAMI / ANSI / ISO 10993-1:2018, recognition number 2-258 included the extent of recognition.
The connector to High-Pressure gas is in accordance with CGA V-5:2008, Recognition Number 1-81.

Conclusion for Substantial Equivalence

The proposed Servo-air Lite Ventilator System and the predicate device Respironics V60 (K102985) have the equivalent indications for use and no new questions of safety and effectiveness that pose significant safety or effectiveness concerns are raised. Additional reference devices have been used to demonstrate substantial equivalence for specific features.

Maquet Critical Care has conducted risk analysis and performed necessary verification and validation activities to demonstrate that the design output of the modified device meet the design input requirements and the appropriate product standards.

Maquet Critical Care has concluded that the Servo-air Lite Ventilator System is substantially equivalent to the predicate devices Respironics V60 (K102985).