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

Re: K201874
Trade/Device Name: Servo-u Ventilator System 4.1, Servo-n Ventilator System 4.1, Servo-u MR Ventilator System 4.1
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: July 6, 2020
Received: July 7, 2020

Dear Mark 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,

Brandon Blakely, PhD
Acting Assistant Director
DHT1C: Division of ENT, 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: 06/30/2020
See PRA Statement below.

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

Device Name
Servo-u Ventilator System 4.1
Servo-n Ventilator System 4.1
Servo-u MR Ventilator System 4.1

Indications for Use *(Describe)*

The Servo-u Ventilator System is:
- intended for respiratory support, monitoring and treatment of neonatal, pediatric and adult patients
- to be used only by healthcare providers
- to be used only in professional healthcare facilities and for transport within these facilities

The Servo-n Ventilator System is:
- intended for respiratory support, monitoring and treatment of neonatal and pediatric patients
- to be used only by healthcare providers
- to be used only in professional healthcare facilities and for transport within these facilities

The Servo-u MR Ventilator System is:
- intended for respiratory support, monitoring and treatment of neonatal, pediatric and adult patients
- to be used only by healthcare providers
- to be used only in professional healthcare facilities and for transport within these facilities
- to be used in MR environment according to specified conditions
  - with 1.5 T or 3 T MR scanners
  - outside magnetic fields >20 mT/200 Gauss

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	Mr. David Ardanius Regulatory Affairs Manager Phone: direct: (011) 46 10 335 7300 Email: david.ardanius@getinge.com
Application Correspondent:	Mr. Mark N. Smith Manager, Regulatory Affairs Getinge 45 Barbour Pond Drive Wayne, NJ 07470 Email: mark.n.smith@getinge.com Phone: 585-272-5274

Date prepared: August 31, 2020

Trade Name:	**Model:**	**Model no:**
Servo-u 4.1 Ventilator System	Servo-u	66 94 800
Servo-n 4.1 Ventilator System	Servo-n	66 88 600
Servo-u MR 4.1 Ventilator System	Servo-u MR	68 88 800

Device Classification

Common Name	Ventilator, continuous, facility use
Classification Number	CBK
Class	II
Regulation Number	21 CFR 868.5895

Predicate Device Identification

Maquet Servo-u/n Ventilator System	K180098

Reference Device Identification

Maquet Servo-i Ventilator System	K123149
Nihon Kohden NKV-550	K181695
Hamilton-G5	K193228

Indications for Use

The Servo-u/n/u MR Ventilator Systems are:

- intended for respiratory support, monitoring and treatment of neonatal, pediatric and adult patients (adult not applicable for Servo-n)
- to be used only by healthcare providers
- to be used only in professional healthcare facilities and for transport within these facilities

The Servo-u MR Ventilator System to be used in MR environment according to specified conditions:

- with 1.5 T or 3 T MR scanners
- outside magnetic fields >20 mT/200 Gauss

Device Description
The Servo-u/n/u MR Ventilator Systems 4.1 consist 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-u/n/u MR Ventilator Systems 4.1 are based on the cleared predicate device Servo-u/n Ventilator Systems 2.1 (K180098) with some improvements. The ventilation modes in the Servo-u/n/u MR 4.1 are the same as the predicate device. Standard configurations of available modes and optional modes do differ between the devices, i.e. Servo-u/n/u MR 4.1.

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

The Electrical activity of the diaphragm (Edi) is a measurement of the patients own breathing efforts. The Edi functionality makes it possible to monitor Edi activity in all ventilation modes, High Flow therapy as well as in Standby.

NAVA stands for Neurally Adjusted Ventilatory Assist and is a supported mode of ventilation based on the Edi, delivering assist in proportion to and synchronized with the patient's respiratory drive. NAVA is available as an invasive and a non-invasive mode. The included parts related to this mode, such as Edi module and Edi catheters are identical to the cleared predicate devices Servo-u/n 2.1 (K180098).

Servo-u/n contain a dedicated controller circuit for the Aerogen Solo nebulizer (included as standard). It is identical to the cleared predicate devices Servo-u/n 2.1 (K180098). Not available on Servo-u MR.

Accessories for CO_2 monitoring and flow and pressure measurements at the Y piece (Y sensor) are integrated as options. It is identical to the cleared predicate devices Servo-u/n 2.1 (K180098).

The Servo-u/n/u MR Ventilator Systems will produce visual and audible alarms if any parameter varies beyond pre-set or default limits and log alarm recordings. The alarm handling is similar to the one used in the cleared predicate devices Servo-u/n 2.1 (K180098).

The Servo-u/n/u MR Ventilator Systems contain provisions for battery modules to supply the system in the case of mains power failure or during intra-hospital transport. The batteries are identical to the one used for the cleared predicate devices Servo-u/n 2.1 (K180098).

COMPARISSON TO PREDICATE

Comparison of Intended Use/Indications Use
The Indications for Use for the proposed Servo-u/n/u MR Ventilator Systems 4.1 are identical to the predicate device Servo-u/n 2.1 Ventilator System (K180098 with the addition of MR environment to Servo-u MR.

MAQUET bases this 510(k) notification on that the Servo-u/n/u MR 4.1 fulfil the appropriate product standards and is substantially equivalent with the already cleared predicate device Servo-u/n Ventilator Systems 2.1 (K180098).

Comparison of Technology Characteristics
The Servo-u/n/u MR Ventilator Systems 4.1 are modifications of the previously cleared Servo-u/n Ventilator Systems 2.1 (K180098).

The following changes have been made to Servo-u/n/u MR Ventilator Systems 4.1 compared to the cleared predicate device Servo-u/n Ventilator Systems 2.1 (K180098):

- ***Servo-u MR, Mechanical adaptions and Magnetic Field Indicator***

Compared to the predicate device, a magnetic field indicator and mobile cart with auto-lock are added. Also the panel is modified.

The patient unit is permanently attached to the mobile cart and can therefore not be detached once assembled.

Cable Shielding ferrites have been added to the panel, panel cable and panel connector to protect the components from the induced magnetic field. The panel cable is fixated in the panel to increase the robustness.

The panel arm on the user interface is not adjustable. However, it is possible to rotate and tilt the user interface.

A Magnetic Field Indicator (MFI) is introduced to the system. The intent of the MFI is to assist the user when placing the ventilator in the MR environment by continuously indicating the magnetic field.

An auto-lock handle is added. When the handle is released, the brakes automatically lock all four wheels. When the handle is depressed, the wheels are unlocked, enabling the user to move the ventilator.

Additionally, the nebulizer port is plugged and it is not possible to attach drawers or place compressor mini on the mobile cart.

- ***Software and user interface***

Software modifications have been made to add new functionality such as:

- OLT trends (Open Lung Tool)
- OLT RM (Recruitment maneuver)
- OLT SRM (Stepwise RM)
- TP (Transpulmonary pressure)
- SI (Stress index)
- Heliox
- The possibility of setting PEEP to 0 cmH_2O
- Minor improvements of the Total PEEP and Dynamic compliance calculations and the Circuit compliance compensation.
- Minor corrections

The Servo-u/n/u MR software is considered a Major Level of Concern. Software verification was performed according to FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and according to the standard IEC 62304 "Medical device software - Software life-cycle processes".

- ***Components***

The label of the Y sensor module pressure port is changed from P_{AW} to $P_{AUX.}$
Compared to the predicate device an adapter for Heliox connection is added.
CO2 module updated due to last-time-buy.
Y-piece, angled label change to disposable
Increased stability of Support arm by added clamp holder

- ***Alarms***

The following adjustments and changes have been implemented for the alarms.

The algorithm linked to triggering of the alarm "Patient circuit disconnected" has been improved and split into two alarm types of the same priority; "Patient circuit disconnected" and "Check Tubing".

Minor improvements of the alarm handling for the Y sensor

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

- Specification and system-level verification 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 80601-2-12:2011, 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
- IEC 62133-1:2017, Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications - Part 1: Nickel Systems

The connector to High-Pressure gas is in accordance with CGA V-5:2008, Recognition Number 1-81.
Biocompatibility evaluation of the Servo-u/n/u MR 4.1 is in accordance with ISO 10993-1:2018, recognition number 2-258 and ISO 18562-1:2017, recognition number 1-134.

Processing of Health Care Products evaluation of the Servo-u/n/u MR 4.1 is in accordance with ANSI AAMI ISO 17664:2017, recognition number 14-515 included the extent of recognition.

Conclusion for Substantial Equivalence
The subject devices and the predicate device have the same intended use. There are no new type questions of safety and effectiveness for the subject devices that pose significant safety or effectiveness concerns as compared to the cleared predicate device. MAQUET has conducted risk analysis and performed the necessary verification and validation activities to demonstrate that the design outputs meet the design input requirements and the appropriate product standards. MAQUET concludes that the performance data for the subject devices shows that they are substantially equivalent to the cleared predicate device.