March 19, 2019

Maquet Critical Care AB
% Mark Dinger
Sr. Regulatory Affairs Specialist
Maquet Medical System USA
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K180098
Trade/Device Name: SERVO-U/n Ventilator System 2.1
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: February 11, 2019
Received: February 15, 2019

Dear Mark Dinger:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180098

Device Name
SERVO-U/n Ventilator System 2.1

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
For NAVA and Edi monitoring, it is in addition intended:
• to provide monitoring of the patient's breathing drive
• to improve synchrony between the ventilator system and patient when the electrical signal from the brain to the diaphragm is active
• for use on all patients with no contraindication for insertion/exchange of a nasogastric tube
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
For NAVA and Edi monitoring, it is in addition intended:
• to provide monitoring of the patient's breathing drive
• to improve synchrony between the ventilator system and patient when the electrical signal from the brain to the diaphragm is active
• for use on all patients with no contraindication for insertion/exchange of a nasogastric tube

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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510(K) SUMMARY

510(k) SUMMARY
as required by section 21 CFR 807.92

Submitter Name & Address
Maquet Critical Care AB
Röntgenvägen 2
SE-171 54 Solna, Sweden
Phone: (011) 46 10 335 7300

Contact Persons for this submission: Jerker Åberg
Regulatory Affairs Manager
Phone: direct: (011) 46 10 335 7300
Email: jerker.aberg@getinge.com

Application Correspondent: Mark Dinger
Sr. Regulatory Affairs Specialist
Maquet Medical Systems USA
45 Barbour Pond Drive
Wayne, NJ 07470
Email: mark.dinger@getinge.com
Phone: 973-709-7691
Fax: 973-909-9954

510(k) Number K180098

Date prepared: March 18, 2019

Trade Name:	**Model:**	**Model no:**
SERVO-U/n Ventilator System 2.1	SERVO-U	66 94 800
	SERVO-n	66 88 600

Device Classification

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

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
SERVO-U/n Ventilator System version 1.1	K151814

Reference Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
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Device Description

The SERVO-U/n 2.1 is available in two models, SERVO-U and SERVO-n. The SERVO-U/n 2.1 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-U/n 2.1 is based on the cleared predicate device SERVO-U/n 1.1 (K151814), with some improvements. The ventilation modes in the SERVO-U/n 2.1 are similar as in the predicate device, even though the standard configurations of available modes and optional modes differ between the devices, i.e. SERVO-U, SERVO-n and the cleared predicate device SERVO-U/n 1.1.

The ventilator delivers controlled or supported breaths to the patient, with constant flow, constant pressure or pressure proportional to the Edi signal (the electrical activity of the diaphragm) of the patient, using a set oxygen concentration.

SERVO-U/n contains a dedicated controller circuit for the Aerogen Pro and Solo nebulizers (included as standard).

Accessories for CO_2 monitoring and flow and pressure measurements at the Y piece (Y sensor) are integrated as options.

The SERVO-U/n Ventilator System will produce visual and audible alarms if any parameter varies beyond pre-set or default limits and produce 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.

System parts:

The SERVO-U/n Ventilator System consists of the following parts:

- User interface, where user interactions are performed.
- Patient unit with all connections to the patient, to power and gases.
- Mobile cart, on wheels, for using the ventilator on either the left or the right side of the patient.

Indications for Use

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

For NAVA and Edi monitoring, it is in addition intended:

- to provide monitoring of the patient's breathing drive
- to improve synchrony between the ventilator system and patient when the electrical signal from the brain to the diaphragm is active
- for use on all patients with no contraindication for insertion/exchange of a nasogastric tube

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

For NAVA and Edi monitoring, it is in addition intended:

- to provide monitoring of the patient's breathing drive
- to improve synchrony between the ventilator system and patient when the electrical signal from the brain to the diaphragm is active
- for use on all patients with no contraindication for insertion/exchange of a nasogastric tube

The second part of the indications for use is related to the NAVA (Neurally Adjusted Ventilatory Assist) ventilation mode which is a supported mode for SERVO-U/n that uses the Edi signal (the electrical activity of the diaphragm) as an addition to the flow/pressure trigger to synchronize the patient efforts with the onset and cycle off of supported breaths. NAVA is available in invasive and non-invasive modes.

Intended use of the Device
Intended use is identical to indications for use.

1.1 CHANGES AND SUBSTANTIAL EQUIVALENCE DISCUSSION

Comparison of Intended Use
The intended use/indication for use for the proposed device, SERVO-U/n 2.1 Ventilator System, is identical to the predicate device SERVO-U/n 1.1 (K151814).

Comparison of Technology Characteristics
The SERVO-U/n 2.1 is based on the cleared predicate device SERVO-U/n 1.1 (K151814), with some improvements noted in the description below. Software algorithms for ventilation and alarms are re-used. Furthermore, the ventilation modes in the SERVO-U/n 2.1 are similar as in the cleared predicate device, even though the standard configurations of available modes and optional modes differ between the devices.

The following changes have been made to SERVO-U/n 2.1 compared to the cleared predicate device SERVO-U/n 1.1 (K151814):

- Software and the Graphical User Interface (GUI) have been updated to include the lock/unlock functionality.
- High Flow Therapy (HFT) has been added as a new optional breathing therapy.
- SERVO Compass has been added as a visual clinical support tool to facilitate protective ventilation.
- Implementation of Volume Control improvements including decelerating flow and de-activation of flow adaptation.
- Implementation of NAVA improvements by removing NAVA(PS) as backup and some minor additional changes.
- Addition of configuration SERVO-U Adult. This adds a possibility to market SERVO-U with a SW configuration with fewer ventilation modes compared to predicate device.
- Changes in Alarm sound to comply with standard AAMI ANSI IEC 60601-1-8:2006 + A1:2012. Verification to comply with A1:2012 of IEC 60601-1:2005 and A1:2012 of AAMI ANSI IEC 60601-1-8:2006 , updated test reports and CB certifications available.

- Changes of circuit board for expiratory flow measurement, including HW and SW updates, due to LTB. Renaming from PC2004 to PC2024. Functionality is unchanged.
- Material changes in the filter in the patent gas pathway. Addition of alternative pressure sensors in gas pathway.
- Cleaning instructions have been updated with additional cleaning agents.
- Minor usability improvements for alarm handling
- The battery runtime has been increased in the IFU from 45 min to 1 hour.
- Minor improvements of the PRVC mode.
- Improvements of internal software process interaction and supervision.

Similarities and differences
The subject device is similar in all respects, except from what is stated above, to the predicate device.

Non-clinical Testing and Performance
Support for the substantial equivalence of the SERVO-U/n 2.1 to the cleared predicate device SERVO-U/n 1.1 (K151814) is provided as a result of design verification and bench testing.
The design verification activities consist of:

- Code review and static code analysis
- Unit tests
- Integration tests
- System tests (including safety related functions from risk analysis)
- Free User Testing (FUT)
- Regression testing
- Verification of applicable product standards

The following product standards are included in the verification:

- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, Recognition Number 19-4.
- IEC 60601-1-2 Edition 3: 2007-03, Recognition Number 19-1.
- IEC 60601-1-2:2014 RFID Immunity \ AIM Standard 7351731 Rev 1
- AAMI ANSI IEC 60601-1-8:2006 & A1:2012, Recognition Number 5-92.
- ISO 80601-2-12:2011, Recognition Number 1-98.
- ISO 80601-2-55:2011, Recognition Number 1-96.
- EN13544-1:2007, this standard is not recognized by FDA.

Biocompatibility evaluation of the SERVO-U/n 2.1 is in accordance with AAMI / ANSI / ISO 10993-1:2009, recognition number 2-156 included the extent of recognition. Biocompatibility testing (i.e. cytotoxicity, sensitization, genotoxicity and implantation) including extractables and leachables and evaluation/risk assessment has been performed

regarding exposure to volatile organic compounds, particulate matter, colorants and leachable (in case of condensate).

The connector to High-Pressure gas is in accordance with CGA V-5:2008, Recognition Number 1-81.

Design validation has been performed in order to ensure that the product meets both its intended use and user needs, including usability.

Bench testing of waveforms have been performed to verify substantial equivalence to the predicate device.

Design verification and validation have demonstrated that the SERVO-U/n 2.1 performs within its specifications and within the limits of the applied product performance standards.

Clinical Investigation
No clinical investigation has been performed since it has been concluded based on literature data, state of the art knowledge and applicable product standards that SERVO-U/n 2.1 has no new clinical aspects or risks which are not already discussed and evaluated in the 510(k) submission for the cleared predicate device SERVO-U/n 1.1 (K151814).

1.1.1 Conclusion for substantial equivalence

SERVO-U/n 2.1 and the predicate device SERVO-U/n 1.1 (K151814) have identical intended use. There are no new type questions of safety and effectiveness for SERVO-U/n 2.1 as compared to the predicate device SERVO-U/n 1.1 (K151814). 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 SERVO-U/n 2.1 shows that it is substantially equivalent to the cleared predicate device SERVO-U/n 1.1 (K151814).