DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 21, 2015

Maquet Critical Care Ab
% Ms. Lia Gonzalez
Regulatory Affairs Specialist
Maquet Medical Systems USA
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K151814
Trade/Device Name: Servo-U and Servo-n Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: November 17, 2015
Received: November 18, 2015

Dear Ms. Lia Gonzalez:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151814

Device Name
SERVO-U and SERVO-n Ventilator System

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.

510(k) SUMMARY

as required by section 21 CFR 807.92

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Date prepared: November 11, 2015

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

Device Classification

Common Name	*Classification Product Code*	*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-i Ventilator System version 7.0	K123149

Indications for Use of the Device

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. These ventilation modes are identical in the SERVO-U/n Ventilation system to the already cleared predicate device SERVO-i Ventilator System (K123149). Furthermore, the included hardware parts Edi module and Edi catheters are also identical to the cleared predicate device SERVO-i Ventilator System (K123149).

	SUBJECT DEVICE	***SUBJECT DEVICE***	***Predicate Device***	***Conclusion/Comparison***
Device	**SERVO-U Ventilator**	**SERVO-n Ventilator**	**SERVO-i Ventilator**	
510(k) Number	Pending	Pending	K123149	
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 SERVO-i Ventilator System is intended for treatment and monitoring of patients in the range of neonates, infants, and adults with respiratory failure or respiratory insufficiency. SERVO-i is a ventilator system to be used only by healthcare providers in hospitals or healthcare facilities and for in-hospital transport. The added indications for use of the NAVA option is when the electrical signal from the brain to the diaphragm is intact; NAVA will improve synchrony between the ventilator and patients with no contraindication for insertion /exchange of a Naso-Gastric tube.The SERVO-i Ventilator is classified as MR Conditional for 1.T, 1.5T and 3T MR scanners. This means that it is safe to use in the MR environment if the conditions in the MR Environment Declaration for SERVO-i are met. The SERVO-i Ventilator System with Heliox option is indicated for use with the delivery of Air, Oxygen, or Heliox (a mixture of Helium and Oxygen).	Similar- the indications for use are rephrased compared to the cleared predicate device. Difference- SERVO-n is intended for neonatal and pediatric patients only. Difference- SERVO-U and SERVO-n are not equipped with MR or Heliox options.

Device Description

The SERVO-U/n Ventilator System is available in two models, SERVO-U and SERVO-n. The SERVO-U/n 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-U/n Ventilator System is built on the same architecture as the cleared predicate device SERVO-i Ventilator System (K123149). The ventilation modes in the SERVO-U/n Ventilator System are identical to the ventilation modes in the cleared 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-i Ventilator System (K123149).

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.

NAVA (Neurally Adjusted Ventilatory Assist) is a supported mode for SERVO-U/n that uses the Edi signal 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. These ventilation modes are identical in the SERVO-U/n Ventilation system and the cleared predicate device SERVO-i Ventilator System (K123149). Furthermore, the included hardware parts Edi module and Edi catheters are also identical to the ones used for the cleared predicate device SERVO-i Ventilator System (K123149).

SERVO-U/n contains a dedicated controller circuit for the Aerogen Pro and Solo nebulizers (included as standard). In the cleared predicate device SERVO-i Ventilator System (K123149) the corresponding nebulizer function is available as an optional module.

Accessories for CO_2 monitoring and flow and pressure measurements at the Y piece (Y sensor) are integrated as options. The CO_2 monitoring option is updated with Capnostat 5 and the Y sensor is based on a new technology and measuring function compared to the corresponding options for the cleared predicate device SERVO-i Ventilator System (K123149).

The SERVO-U/n Ventilator System will produce visual and audible alarms if any parameter varies beyond preset or default limits and produce alarm recordings. The alarm handling is very similar to the one used in the cleared predicate device SERVO-i Ventilator System (K123149), except the possibility to set alarm off for leakage related alarms in Neonatal Patient category when leakage compensation is activated. Additionally, an Inspiratory tidal volume (VT) too high alarm has been added in the

neonatal patient category and three alarms have been removed in the Non-invasive modes.

The system contains provisions for battery modules to supply the system in the case of mains power failure or during in-hospital transport. The batteries are identical to the one used for the cleared predicate device SERVO-i Ventilator System (K123149).

System parts:

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

- User interface, where all 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.

SERVO-U/n Ventilator System on mobile cart

Comparison and substantial equivalence statement

Comparison of Indication for Use

The intended use/indication for use for the proposed device, SERVO-U/n Ventilator System, is very similar since the general purpose of the device and the functions are unchanged compared to the intended use of the cleared predicate device SERVO-i Ventilator System (K123149). The intended use/indication for use is rephrased and there are only two minor differences compared to the cleared predicate device SERVO-i Ventilator System (K123149). The first one is that SERVO-n is intended for neonatal and pediatric patients only. The second one is that SERVO-U and SERVO-n cannot be equipped with MR or Heliox options available for SERVO-i. Note that not all SERVO-i devices are possible to use in MR environment (i.e. it requires a specially adapted SERVO-i). MAQUET believes that these two differences will not change the intended therapeutic or monitoring use of the SERVO-U/n compared to the cleared predicate device SERVO-i Ventilator System (K123149).

Comparison of Technology Used

The SERVO-U/n Ventilator System is built on the same architecture as the cleared predicate device SERVO-i Ventilator System (K123149). Software algorithms for ventilation and alarms are re-used. Furthermore, the ventilation modes in the SERVO-U/n Ventilator System are identical to the ventilation modes in the cleared predicate device, even though the standard configurations of available modes and optional modes differ between the devices, SERVO-U, SERVO-n and the cleared predicate device SERVO-i Ventilator System (K123149).

The following changes have been made compared to the cleared predicate device SERVO-i Ventilator System (K123149):

- Software and the Graphical User Interface (GUI) have been updated to improve the interaction between the user and the Ventilation System. The updated GUI includes context-based guidance and intuitive user interaction for all functions. The user interface panel is new compared to the one used for the cleared predicate device SERVO-i Ventilator System (K123149).

- Software platform and microprocessors are upgraded to more modern versions to enable functional growth in the future.

- The lower limit for patient weight in neonatal patient category has been decreased from 0.5 kg to 0.3 kg.

- The flow measuring device in the Y sensor is a hot wire anemometer (HWA) type sensor. In the Y sensor of the cleared predicate device the flow measuring technology is based on fixed orifice, differential pressure. The pressure measurement uses the same technology for both devices. The Y sensor monitors flow and pressure and increases the accuracy of the delivered gas at small tidal volumes. The functionality to increase the accuracy of the delivered gas is new compared to the cleared predicate device SERVO-i Ventilator System (K123149).

- The materials included in the breathing circuit that indirectly will be exposed to the patient through the breathing gas are very similar to the materials used in the breathing circuit of the cleared predicate device SERVO-i Ventilator System (K123149). The differences are:

    - two new gray color complexes are used in the polymeric material in the inspiratory channel. However, the polymeric material is identical to the one used for the inspiratory channel in the cleared predicate device.
    - new Y sensor which includes new materials

- The CO_2 analyzer option has been updated to Capnostat 5. Capnostat 5 is an OEM product and it is manufactured by Respironics Novametrix, Inc. (510(k) clearance number K042601).

- In the neonatal patient category, there is a leakage compensation function available in all invasive modes except Bi-Vent/APRV. A leakage compensation function is available in the Non-invasive modes of the cleared predicate device SERVO-i Ventilator System (K123149).

- A new function has been implemented to set alarm off for leakage related alarms in Neonatal Patient category when leakage compensation is activated.

- An Inspiratory tidal volume (VT) too high alarm has been added in the neonatal patient category.

- In NIV modes, the following alarms have been removed in comparison to the cleared predicate device SERVO-i Ventilator System (K123149): “VT inspiratory overrange”, “Inspiratory flow overrange” and “Unreliable Edi signal”.

- SERVO-U and SERVO-n cannot be equipped with MR or Heliox options.

Conclusion
MAQUET believes that the rephrasing and the two minor differences in intended use/indication for use will not affect the therapeutic or monitoring use of the SERVO-U/n compared to the cleared predicate device SERVO-i Ventilator System (K123149). It is concluded that there are no new type questions of safety and effectiveness for the SERVO-U/n Ventilator System as compared to the cleared predicate device SERVO-i Ventilator System (K123149). MAQUET has conducted the 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 has concluded that the performance data for the SERVO-U/n Ventilator System show that it is as safe and as effective as the already cleared predicate device SERVO-i Ventilator System (K123149).

Non-clinical Testing and Performance

Support for the substantial equivalence of the SERVO-U/n Ventilator system to the cleared predicate device SERVO-i Ventilator System (K123149) was provided as a result of risk management and 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 ES 60601-1:2005, Recognition Number 19-5.
- IEC 60601-1-2:2007, Recognition Number 19-1.
- IEC 60601-1-8:2006, Recognition Number 5-86.
- ISO 80601-2-12:2011, Recognition Number 1-98.
- ISO 80601-2-55:2011, Recognition Number 1-96.
- ISO 5356-1:2004, Recognition Number 1-62.
- CGA V-5:2008, Recognition Number 1-81.
- EN13544-1:2007, this standard is not recognized by FDA.

Biocompatibility evaluation of the SERVO-U/n Ventilator System is in accordance with AAMI / ANSI / ISO 10993-1:2009, recognition number 2-156 included the extent of recognition. The biocompatibility testing of new materials is based on Annex A in Blue

book memorandum #G95-1, "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices'—Part 1: Evaluation and Testing"

Biocompatibility testing (i.e. cytotoxicity and sensitization) and evaluation has been performed regarding exposure to volatile organic compounds, particulate matter, introduced colorants and leachable (in case of condensate) for all components with new materials, or composition in materials, that contact the gas pathway to the patient. The patient contact is considered to be prolonged, less than 30 days, external communicating device with tissue contact.

Design validation has been performed in order to ensure that the product meets both its intended use and user needs, including usability. The validation activities included an animal study to evaluate the performance of the Y sensor algorithm at different degrees of humidity and leakage and to evaluate the effect of these two variables on tidal volume measurements. Usability activities, including a large number of formative tests as well as a summative usability validation, have been performed. Potential use errors were identified and estimated in the usability risk analysis process and the obtained information served as basic input to the performed human factors testing.

Design verification and validation have demonstrated that the SERVO-U/n Ventilator System 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 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-i Ventilator System (K123149).

____K151814_____
(Premarket Notification [510(k)] Number)