MAQUET
GETINGE GROUP

K123149

SERVO-i and SERVO-s
510(k) SUMMARY
Prepared in accordance with 21 CFR Part 807.92

JUN 2 0 2014

GENERAL INFORMATION:

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Date prepared: October 4, 2012

DEVICE INFORMATION:

This summary describes the changes performed for the SERVO-i Ventilator System and the SERVO-s Ventilator System.

Trade Name :	**Model:**	**Model no:**
SERVO-i Ventilator System	SERVO-i	64 87 800
	SERVO-s	66 40 440

Device Classification

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

PREDICATE DEVICE INFORMATION:

Legally marketed devices to which equivalence is being claimed	*510(k) #*	*Model of Subject device*
SERVO-i Ventilator system	K073179	SERVO-i
SERVO-i Ventilator system	K041223	SERVO-s

DEVICE DESCRIPTION:

SERVO-i Ventilator System
The SERVO-i Ventilator System (here after called SERVO-i) is intended to provide continuous ventilation for neonate to adult patients in the weight range 0.5-250 kg and with tidal volumes from 2 mL to 4000 mL. SERVO-i 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 ventilator delivers controlled or supported breaths to the patient, with either constant flow or constant pressure, using a set oxygen concentration. SERVO-i will produce visual and audible alarms if vital parameters vary beyond pre-set, or default, limits. The system contains provisions for at least two battery modules to supply the system in the case of mains power failure or during in-hospital transport. The ventilator functionality is controlled by software. The SERVO-i Ventilator System is available in three software versions, Infant, Adult and Universal.

The NAVA (Neurally Adjusted Ventilatory Assist) option is a supported mode for SERVO-i 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. The NAVA option is available in invasive and non-invasive mode.

SERVO-i is MR conditional. The SERVO-i ventilator with MR option have been tested with 1.0, 1.5, 3.0 T scanners without impairing its performance or the image quality of the scanner. Each scanner and its environment form an individual device. The MR Environment Declaration describes how a SERVO-i with MR option can be qualified to be used with an MR scanner forming a safe Medical System. All vital parts of the ventilator have been tested for performance in excessive magnetic fields.

The SERVO-i with Heliox option requires a different mechanical adaptor on the air supply inlet to allow a mixture of Helium and Oxygen to be connected. Furthermore is the software updated to allow safe delivery and monitoring of the Heliox gas mixture.

Accessories for CO_2-monitoring, nebulization and flow monitoring at the Y –piece (Y-sensor) are integrated as options in the SERVO-i and the drivers are controlled by the software in the ventilator.

This 510(k) submission for the SERVO-i include changes to receive a new baseline based on compatibility to the third edition standard package of AAMI/ANSI 60601-1 :2005 and its collateral and particular standards for intensive care ventilators. The submission does also include modifications of the software and hardware to update existing functionalities since the last submission (K073149).

SERVO-s Ventilator System Description
The SERVO-s ventilator system (here after called SERVO-s) is based on the SERVO-i ventilator family platform. SERVO-s ventilation system is a downscaled version based on the SERVO-i ventilator system notified in K041223.
The SERVO-s Ventilator System is intended to provide continuous ventilation for neonate to adult patients in the weight range 2-250 kg and with tidal volumes from 10 mL to 2000 mL. The SERVO-s 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 ventilator delivers controlled or supported breaths to the patient, with either constant flow or constant pressure, using a set oxygen concentration. SERVO-s Ventilator System will produce visual and audible alarms if vital parameters vary beyond preset, or default, limits. The system contains two

internal batteries to supply the system with power in the case of mains power failure or during in-hospital transport. The ventilator functionality is controlled by software. The SERVO-s Ventilator System is available in two software versions, Infant and Adult.

This 510(k) submission for the SERVO-s include changes to receive a new baseline based on compatibility to the third edition standard package of IEC 60601-1 :2005 and its collateral and particular standards for intensive care ventilators. The submission does also include addition of the Infant option, patient weight range 2-10 kg, with tidal volumes from 10 mL to 350 mL and modifications of the software and hardware to update existing functionalities.

DEVICE INDICATIONS FOR USE / INTENDED USE:

SERVO-i Ventilator System Indications For Use
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).

SERVO-s Ventilator System Indications For Use
The SERVO-s 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-s is a ventilator system to be used only by healthcare providers in hospitals or healthcare facilities and for in-hospital transport.

COMPARISON OF INDICATIONS FOR USE:

The Indications for Use for the modified SERVO-i Ventilator System version 7.0 (K123149) are identical to the predicate device, SERVO-i Ventilator System version 4.0.

Note: Version 4.0 is the general software included in the last submission (K073179). The focus of the previous submission was on the Heliox option, and it had therefore not the complete indications for use for the entire Ventilation system included.

The Indication for Use for the modified SERVO-s Ventilator System version 7.0 (K123149) is identical to the predicate device, SERVO-i Ventilator System version 2.0 (K041223).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

SERVO-i Ventilator System
The technological characteristics for the subject device SERVO-i Ventilator System version 7.0 (K123149) with respect to the control mechanism, operating principle, energy type, ergonomics of the patient interface, firmware, environmental specifications and performance specifications are similar to the predicate device, SERVO-i Ventilator System version 4.0 (K073179). The small differences are described below.

Changes according to mandatory requirements in the standards IEC 60601-1:2005, ISO 80601-2-12:2011 and ISO 80601-2-55:2011:

- Update of all accuracy statements, the performance is the same is only the way to measure and present the data that is different.
- Update to Noise level measurement, the performance is the same is only the way to measure and present the data that is different.
- Improved Ingress Protection to IP2, improvements done to the chassi.
- Brakes on all four wheels, (previous only two wheels) to improved mechanical stability to meet new requirements for transport within hospitals.
- Changed Gas inlet pressure specification. Gas inlet max pressure is lowered to comply with the required testing.
- Added measurement of Patient circuit resistance to the Pre-Use Check. Compliance and resistance testing of the patient circuit mandatory in the new standard ISO 80601-2-12.

Other changes to the predicate device:

- Added ventilation mode NIV NAVA, combination of the two cleared ventilation modes NIV (Non-invasive ventilation) and NAVA (Neurally Adjusted Ventilatory Assist).
- Added features:
  - A second RS232 port, identical with the first RS-232 port.
  - Changed built-in nebulizer. The previous SUN nebulizer has been replaced with an Aeroneb nebulizer that also works in battery mode. Nebulization performance is equal.
  - Stress Index, new monitoring parameter. No impact on ventilation performance.

SERVO-s Ventilator System
The technological characteristics for the subject device SERVO-s Ventilator System version 7.0 (K123149) with respect to the control mechanism, operating principle, energy type, ergonomics of the patient interface, firmware, environmental specifications and performance specifications is similar to the predicate device, SERVO-i Ventilator System version 2.0 (K041223). The small differences are described below.

Changes according to mandatory requirements in the standards IEC 60601-1:2005, ISO 80601-2-12:2011 and ISO 80601-2-55:2011:

- Update of all accuracy statements, the performance is the same is only the way to measure and present the data that is different.
- Update to Noise level measurement, the performance is the same is only the way to measure and present the data that is different.
- Improved Ingress Protection to IP21, improvements done to the chassi.
- Brakes on all four wheels, (previous only two wheels) to improve mechanical stability to meet new requirements for transport within hospitals.

- Changed Gas inlet pressure specification. Gas inlet max pressure is lowered to comply with the required testing.
- Added measurement of Patient circuit resistance to the Pre-Use Check. Compliance and resistance testing of the patient circuit mandatory in the new standard ISO 80601-2-12.

Other changes to the predicate device:

- Smaller enclosure and new carrier
- Attachment of the graphic user interface, fixed attachment to the ventilator the predicate device attaches to the mobile cart, a table, railing, or 15-30 mm diameter pipe.
- Power Supply, 2 rechargeable internal battery modules, the predicate device has 2– 6 rechargeable battery modules
- 4 PC boards in Servo-s are similar to the ones in the predicate device but adapted to the change of the new smaller enclosure the other PC boards are identical.
- Infant weight range 2 - 30 kg, the predicate has a lower weight limit of 0.5 kg.
- Tidal volume range 10-2000 mL, the predicate has a range of 2-4000 mL.
- Fewer Ventilation modes and options available

NON-CLINICAL PERFORMANCE DATA:

SERVO-i Ventilator System
Design verification and validation has demonstrated that the SERVO-i performs within its specifications and within the limits of the applied performance standards.

The design verification activities for the modified SERVO-i Ventilator System version 7.0 consist of:

- Requirement verification of affected requirements
- Regression testing
- Code review and static code analysis
- Free User Testing (FUT)
- Verification of applicable product standards
    - IEC 60601-1 :2005
    - IEC 60601-1-2
    - IEC 60601-1-8
    - ISO 80601-2-12
    - ISO 80601-2-55
    - ISO 5356-1
    - CGA V-5

- The scope of the verification activities is dependent upon the scope and volume of changes made to the system software or hardware. All existing and new test cases at the system and subsystem level are listed and a discreet judgment is made regarding which tests must be performed. The test cases are based on system and subsystems functions and requirements specifications.
- The Regression Tests are selected by a risk based analysis which evaluates the impact of the changes on the unchanged system and subsystems.
- The verification testing performed on software changes include static code analysis, as well as code review and test before the code is integrated into the system.
- In addition to the analyses and requirements verification, MAQUET performs "free user testing" on the full system software. Free user testing is conducted at the MAQUET test

laboratory by software testers and clinicians to try and identify software issues that would not be identified during strict requirements testing.
- Verification of applicable standard package for intensive care ventilators is performed by a third party test house according to the CB scheme.

The non-clinical performance data presented in this submission shows that MAQUET has performed the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements. These results support that the modified SERVO-i Ventilation System 7.0 (K123149) is substantially equivalent to the predicate device, SERVO-i Ventilation System 4.0 (K073149).

SERVO-s Ventilator System
Design verification and validation has demonstrated that the SERVO-s performs within its specifications and within the limits of the applied performance standards.

The design verification activities for the modified SERVO-s Ventilator System version 7.0 consist of:
- Requirement verification of affected requirements
- Regression testing
- Code review and static code analysis
- Free User Testing (FUT)
- Verification of applicable product standards
    - IEC 60601-1
    - IEC 60601-1-2
    - IEC 60601-1-8
    - ISO 80601-2-12
    - ISO 80601-2-55
    - ISO 5356-1
    - CGA V-5

- The scope of the verification activities is dependent upon the scope and volume of changes made to the system software or hardware. All existing and new test cases at the system and subsystem level are listed and a discreet judgment is made regarding which tests must be performed. The test cases are based on system and subsystems functions and requirements specifications. Since the differences between the products SERVO-s Ventilator System and SERVO-i Ventilator System are small, tests performed on a SERVO-i ventilation system are also applicable for the SERVO-s ventilator system. Tests on the SERVO-s Ventilator System can be limited to Free User Tests and SERVO-s Ventilator System specific test cases.
- The Regression Tests are selected by a risk based analysis which evaluates the impact of the changes on the unchanged system and subsystems.
- The verification testing performed on software changes include static code analysis, as well as code review and test before the code is integrated into the system.
- In addition to the analyses and requirements verification, MAQUET performs "free user testing" on the full system software. Free user testing is conducted at

the MAQUET test laboratory by software testers and clinicians to try and identify software issues that would not be identified during strict requirements testing.

- Verification of applicable standard package for intensive care ventilators is performed by a third party test house according to the CB scheme.

The non-clinical performance data presented in this submission shows that MAQUET has performed the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements. These results support that the modified SERVO-s Ventilation System 7.0 (K123149) is substantially equivalent to the predicate device, SERVO-i Ventilation System 4.0 (K041223).

CLINICAL PERFORMANCE DATA:

SERVO-i Ventilator System
The functionality added in the SERVO-i Ventilator System version 7.0 (K123149) does not add any new functions that need to be validated by clinical investigation.

Some Validation activities for the SERVO-i Ventilation system have been performed in clinical settings to show that the system meets the Market Requirement Specifications, its intended use, performance and user needs. A summary of Design Validation activities performed since the last 510(k) submission (K073149) in clinical settings are shown below.

Changes to reduce nuisance alarms in NAVA
Updates to the calculation of Respiratory Rate (RR) and Minute Volume (MV) in the NAVA option were performed to reduce nuisance visual and audible alarms. The new software was released in a post market evaluation to 6 sites where 22 patient treatments were recorded. The evaluation at MAQUET showed that the new algorithms did effectively calculate RR and MV while reducing the occurrence of nuisance RR and MV alarms.

Stress Index (SI)
The primary objective was to validate the market requirement "The calculation of SI value shall be based on relevant published articles in clinical journals for the Stress Index option".
This was done by comparing values monitored on a total of ten (10) adult patients with ALI or ARDS with the SERVO-i Stress Index option and with an existing system used in multiple published articles about Stress Index. The results of the comparison with existing system was a <10% discrepancy which was within the acceptance criteria.

Changes to improve Apnea ventilation and alarm behavior in NAVA
Apnea alarms due to common apnea episodes in neonatal patients causing nuisance apnea alarms in NAVA triggered an update to the algorithm for how the switching between NAVA and backup ventilation happens and how apnea alarms are activated. The updated software was released to 3 sites in a post market evaluation and during four weeks it was used on patients. 25 clinicians were using it and they filled in a questionnaire that was evaluated by MAQUET showing that the new algorithm for switching between NAVA and Backup is acceptable and reduces nuisance alarms. The conclusion of the evaluation is that the new Back Up option within the NAVA and NIV NAVA modes meets the intended use and user needs.

SERVO-s Ventilator System

The functionality added in the SERVO-s Ventilator System version 7.0 (K123149) does not add any new functions that need to be validated by clinical investigation.

CONCLUSION FOR SUBSTANTIAL EQUIVALENCE:

MAQUET believes the modifications included since the last submission does not affect the indications for use nor alter the fundamental scientific technology of the device.

MAQUET has conducted risk analysis and performed necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements.

MAQUET has concluded that the modified SERVO-i Ventilator System version 7.0 (K123149) is substantially equivalent to the predicate device, SERVO-i Ventilator System version 4.0 that includes the Heliox option (K073179) and the modified SERVO-s Ventilator System version 7.0 (K123149) is substantially equivalent to the predicate device, SERVO-i Ventilator System version 2.0 (K041223).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2014

Maquet Critical Care AB
c/o Whitney Törning
Director Regulatory Affairs
Maquet Medical Systems USA
45 Barbour Pond Drive
Wayne, NJ 07470

Re: K123149

Trade/Device Name: SERVO-i and SERVO-s Ventilator System
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, continuous, facility use
Class: II
Product Code: CBK
Dated: March 31, 2014
Received: April 1, 2014

Dear Ms. Törning:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K123149

Device Name
SERVO-i Ventilator System

Indications for Use *(Describe)*
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.

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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).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Anya C. Harry -S
2014.06.13
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