



June 18, 2020

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

Re: K192604

Trade/Device Name: Servo-air 4.0 Ventilator System  
Regulation Number: 21 CFR 868.5895  
Regulation Name: Continuous Ventilator  
Regulatory Class: Class II  
Product Code: CBK  
Dated: May 15, 2020  
Received: May 18, 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

James J. Lee Ph.D.  
Assistant Director  
DHT1C: Division of ENT, Sleep Disordered  
Breathing, Respiratory and  
Anesthesia Devices  
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Respiratory, ENT and Dental Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K192604

Device Name

Servo-air 4.0 Ventilator System

Indications for Use (Describe)

The Servo-air ventilator system is

- intended for respiratory support, monitoring and treatment of 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

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
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Application Correspondent:	Mr. Mark N. Smith Manager, Regulatory Affairs Getinge 45 Barbour Pond Drive Wayne, NJ 07470 Email: <a href="mailto:mark.n.smith@getinge.com">mark.n.smith@getinge.com</a> Phone: 585-272-5274

Date prepared: September 13, 2019

Updated: May 7, 2020

**Trade Name:**  
Servo-air 4.0 Ventilator System

**Model:**  
Servo-air

**Model no:**  
68 82 000

**Device Classification**

Common Name	Ventilator, continuous, facility use
Classification Number	CBK
Class	II
Regulation Number	21 CFR 868.5895
510(k) Number	K192604

**Predicate Device Identification**

Maquet Servo-U/n Ventilator System K180098

**Reference Device Identification**

NA

**Indications for Use**

The Servo-air ventilator system is:

- intended for respiratory support, monitoring and treatment of 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

**Device Description**

The Servo-air 4.0 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 4.0 Ventilator System is based on the cleared predicate device Servo-U/n 2.1 Ventilator System (K180098), with some modifications. The ventilation modes in the Servo-air 4.0 are the same as the predicate device. Standard configurations of available modes and optional modes do differ between the Servo-air, and the cleared predicate device Servo-U/n 2.1.

The ventilator delivers controlled or supported breaths to the patient, with constant flow, constant pressure, using a set oxygen concentration.

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

The Servo-air 4.0 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.

**COMPARISSON TO PREDICATE**

	<i>PREDICATE DEVICE</i>	<i>SUBJECT DEVICE</i>	<i>Comment</i>
<b>510(k) Number</b>	K180098	K192604	-
<b>Device name</b>	SERVO-U 2.1	Servo-air 4.0	-
<i>Manufacturer</i>	Maquet Critical Care AB	Maquet Critical Care AB	Identical
<i>Device Classification</i>	CBK	CBK	Identical
<i>Indications for Use</i>	<p>The SERVO-U 2.1 ventilator system is:</p> <ul style="list-style-type: none"> <li>intended for respiratory support, monitoring and treatment of neonatal, pediatric and adult patients</li> <li>to be used only by healthcare providers</li> <li>to be used only in professional healthcare facilities and for transport within these facilities</li> </ul> <p>For NAVA and Edi monitoring, it is in addition intended:                      *to provide monitoring of the patient's breathing drive                      *to improve synchrony between the</p>	<p>The SERVO-air 4.0 ventilator system is:</p> <ul style="list-style-type: none"> <li>intended for respiratory support, monitoring and treatment of pediatric and adult patients</li> <li>to be used only by healthcare providers</li> <li>to be used only in professional healthcare facilities and for transport within these facilities</li> </ul>	<p>Identical for included parts</p> <p>Neonatal patient category excluded for subject device</p> <p>No NAVA and Edi monitoring for subject device)</p>

	<b>PREDICATE DEVICE</b>	<b>SUBJECT DEVICE</b>	<b>Comment</b>
<b>510(k) Number</b>	K180098	K192604	-
<b>Device name</b>	SERVO-U 2.1	Servo-air 4.0	-
	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		
<i>Patient range</i>	Neonatal to adult patient populations	Pediatric to adult patient populations	Identical for included parts  Reduced; Neonatal patient category excluded for subject device
<i>Ventilation Modes</i>	<ul style="list-style-type: none"> <li>● Volume Control (VC)</li> <li>● Pressure Control (PC)</li> <li>● Volume Support (VS)</li> <li>● Pressure Support (PS)</li> <li>● Pressure Support (CPAP)</li> <li>● Pressure Regulated Volume Control (PRVC)</li> <li>● SIMV (SIMV(PC)+PS, SIMV(PRVC)+PS, SIMV(VC)+PS)</li> <li>● Automode (PC-PS, PRVC-VS, VC-VS)</li> <li>● Bi-Vent/APRV</li> <li>● NIV (NIV PC, NIV PS)</li> <li>● NAVA</li> <li>● NIV NAVA</li> <li>● Nasal CPAP</li> </ul>	<ul style="list-style-type: none"> <li>● Volume Control (VC)</li> <li>● Pressure Control (PC)</li> <li>● Volume Support (VS)</li> <li>● Pressure Support (PS)</li> <li>● Pressure Support (CPAP)</li> <li>● Pressure Regulated Volume Control (PRVC)</li> <li>● SIMV (SIMV(PC)+PS, SIMV(PRVC)+PS, SIMV(VC)+PS)</li> <li>● Automode (PC-PS, PRVC-VS, VC-VS)</li> <li>● Bi-Vent/APRV</li> <li>● NIV (NIV PC, NIV PS)</li> </ul>	Identical for included parts  NAVA, NIV NAVA and Nasal CPAP are not included in subject device.
<i>Breathing Therapies</i>	● High Flow therapy	● High Flow therapy	Identical

### Comparison of Intended Use/Indications Use

There are no changes to the Intended Use or Indications for Use between the subject device and the predicate device, with exception to the removal of NAVA which is not part of the indications for use for the subject device.

### Comparison of Technology Characteristics

The Servo-air 4.0 is based on the cleared predicate device Servo-U/n 2.1 (K180098), with adaptations to be wall-gas independent, and modifications noted in the description below. Software algorithms for ventilation and alarms are the same. Furthermore, the ventilation modes in the Servo-air 4.0 are the same as the cleared predicate device.

The following changes have been made to Servo-air 4.0 compared to the cleared predicate device Servo-U/n 2.1 (K180098):

- ***Mechanics and attachment of the panel***

Compared to the predicate device the panel has been changed from a 15” capacitive touch screen to a 12” resistive touch screen. The general layout, functionality and screen resolution (1024x768) remains the same compared to the subject device.

The panel is fixed to the device via hinges instead of being mounted to either the mobile cart, a table or railing, as for the predicate device. As part of the change of panel changed has also been done to the PCBs.

The alarm indicator on the panel of the subject device flashes with the same colors and frequency as the alarm indicator on the screen, compared to the predicate device where the lamp does not flash together with the alarm.

The subject device has different physical dimensions. The casing has been changed from cast aluminum to steel and plastic.

The carrier is based on the same system as the predicate device, but the shelf and the pillar attached to the base of the carrier has been modified to fit the dimensions of the subject device.

- ***Software and user interface***

Software updates have been made to accommodate the modifications to the system. The Servo-air 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***

Compared to the predicate device the Handle, Mounting kit for Compressor Mini on Mobile Cart, and Pendant/bed holder have been removed. The handle is now integrated in the design of the subject device which is also not intended to be bedside mounted and thus the Pendant/bed holder is removed. The Compressor Mini is not an accessory for the subject device so the mounting kit is excluded.

The following components have been changed; Support Arm, Mobile cart, Humidifier Holder and shelf base to accommodate the physical changes to the cart.

New components specific for the subject device include the battery module, battery charger, cabinet, air inlet filter and dust filter.



- **Power system**

The subject device maximum power consumption has increased from 80W to 100W and the power supply electronics have been modified to accommodate this.

The battery has been changed from NiMH to Li-ion batteries. However, the battery system backup time range for the subject device is within the range specified for the predicate device.

- **Blower module**

The Servo-air adds the use of a turbine/blower module with an ambient humidity and temperature sensor. The turbine generates a controlled airflow from the ambient air and is controlled by the blower module. An air flow meter measurement of the mixed (air+O<sub>2</sub>) gas flow is used.

As a result of these changes some performance specifications are also changed for the subject device.

1. The noise level has increased from <40dB (LpA) to <49dB (LpA) and from <51db (LWA) to <57dB (LWA), compared to the predicate device. These levels are still below the recommendations described in ISO 60601-1-8.
2. The air supply performance has been improved so that the ventilator can supply 240 l/min.
3. The Maximum pressure setting has been reduced from 120 to 100 cmH<sub>2</sub>O. The maximum airway pressure is consequently also reduced from 125 to 100 cmH<sub>2</sub>O. These changes do not have any significant clinical impact, since in clinical use 100 cmH<sub>2</sub>O is already considered high.
4. The upper limit for tidal volume Air/O<sub>2</sub> has been changed from 4000 ml to 2000 ml for the adult patient category. For the pediatric patient category the lower limit has been raised from 10 ml to 20 ml.
5. The upper limit for monitored inspiratory tidal volume Air/O<sub>2</sub> has been lowered from 4000 ml to 2000 ml for the adult patient category. For the pediatric patient category the lower limit has been raised from 10 ml to 20 ml.
6. The HFT flow range for the pediatric patient category has been change from 0.5 – 30 l/min to 2 – 30 l/min.

- ***Pre-use check***

The pre-use check has been adapted to the design changes for the subject device.

### **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

#### 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
- EN13544-1:2007, this standard is not recognized by FDA

Biocompatibility evaluation of the Servo-air 4.0 is in accordance with AAMI / ANSI / ISO 10993-1:2009, recognition number 2-156 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 subject device and the predicate device have the same intended use. There are no new type questions of safety and effectiveness for the subject device 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 device shows that it is substantially equivalent to the cleared predicate device.