October 21, 2019

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

Re: K182862
Trade/Device Name: Servo Guard
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: Class II
Product Code: CAH
Dated: September 19, 2019
Received: September 20, 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/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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K182862

Device Name
Servo Guard

Indications for Use *(Describe)*

The Servo Guard is a bacterial/viral filter for applications in respiratory care.The filter is intended to be used in patient circuits to reduce the spread of viruses and bacteria from patient to patient/personnel and to protect the patient circuits and ventilators from contamination. The filter shall only be used with the ventilators Servo-u, Servo-n, Servo-i and Servo-s.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

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Date prepared: September 19th, 2019

Trade Name:	**Model no:**
Servo Guard	6595487

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Breathing Circuit Bacteria Filter	CAH	II	21 CFR 868.5260

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Servo Guard Model number 64 81 290 EH88E	K030071

Indications for Use
The Servo Guard is a bacterial/viral filter for applications in respiratory care. The filter is intended to be used in patient circuits to reduce the spread of viruses and bacteria from patient to patient/personnel and to protect the patient circuits and ventilators from contamination. The filter shall only be used with the ventilators Servo-u, Servo-n, Servo-i and Servo-s.

Device Description

A Breathing Circuit Bacteria Filter is intended to protect from contamination as well as to reduce particles such as dust and microbiological matters from gases used in the patient circuit of a respiratory device. The bacterial/viral filter is a disposable accessory normally used on the expiratory limb of the ventilator breathing system to reduce possible cross contamination between patient and equipment and between patient and patient. It can also be used on the inspiratory pipe, in order to reduce dust particles to the patient.

Figure 1 Servo Guard filter with water trap

Technological Characteristics

Shown below are a comparison of the technological characteristic between the subject device and predicate.

	Cleared Device	*Changed Device*	*Conclusion*
Device	**Servo Guard (model no 64 81 290 EH88E)**	**Servo Guard version (model no 6595487)**	-
Manufacturer	**Maquet Critical Care AB**	**Maquet Critical Care AB**	-
Device Classification Name	Breathing circuit bacterial filter. CAH	Breathing circuit bacterial filter. CAH	-
510(k) Number	K030071	K182862	-
Indications for Use according to the 510(k) Summary	The Servo Guard is an efficient bacterial and viral filter for applications in respiratory care **and anesthesia.** The Servo Guard is a disposable single-use device that provides filtration for reducing possible cross contamination between patient and equipment	The Servo Guard is a bacterial/viral filter for applications in respiratory care. The filter is intended to be used in patient circuits to reduce the spread of viruses and bacteria from patient to patient/personnel and to protect the patient circuits and ventilators from contamination. The filter shall only be used with the ventilators Servo-u, Servo-n, Servo-i and Servo-s.	Similar The intended use of the changed device does not include anesthesia. Limitiation of compatible ventilators.
Physical properties			
Placement	To be used on the expiratory or/and inspiratory limb of a breathing circuit.	To be used on the expiratory or/and inspiratory limb of a breathing circuit.	Identical
Filter Volume	150 ml	150 ml	Identical
Bacterial/viral removal efficiency	>99,999%	>99,999%	Identical
Resistance	1.5 cm H_2O@60 l/min	2.0 cmH_2O@60 l/min (dry) and 2.2 cmH_2O@60 l/min (wet)	different
Connections	ISO 5356-1 M22/F15 (male/female, inlet) ISO 5356-1 F22 (female, outlet)	ISO 5356-1 M22/F15 (male/female, inlet) ISO 5356-1 F22 (female, outlet)	Identical
Weight	60 g	**75 g including water trap**	Similar
Recommended use	Single use, replace every 24 hour	Single use, replace every 24 hour	Identical
Type of filter	mechanical	mechanical	Identical
Shelf life	1 year	**3 years**	Improved
Dimensions	L: H:W = 92 x 66 x 66 mm	L:H:W = 92 x **89**x 66 mm	Similar
Patient range	Neonatal to adult patient populations	Neonatal to adult patient populations	Identical

Summary of Non-clinical testing:

<table>
<tr><th>Test Method</th><th>Purpose</th><th>Acceptance Criteria</th><th>Result</th></tr>
<tr><td>ISO 23328-1
Filter efficiency</td><td>Verify the filter efficiency for the Servo Guard filter</td><td>Servo Guard shall have a filter efficiency > 99.3 % measured in both flow directions</td><td>Filter efficiency: 99,329 %- 99,93%.

Pass</td></tr>
<tr><td>ASTM F2101-14 Standard Test Method for Evaluating the Bacterial Filtration Efficiency</td><td>Verify the bacterial and viral filtration efficiency for the Servo Guard filter</td><td>BFE/VFE filter efficiency shall be > 99.999 %.</td><td>BFE: 99.99951%- 99.999984 %
VFE: 99.99960% - 99.999980

Pass</td></tr>
<tr><td>ISO 18562-2: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications-- Part 2: Tests for emissions of particulate matter</td><td>Verify that the amount of particulate matter are below the acceptance limit</td><td><12 [µg/m3]</td><td>1.4 [µg/m3]
Pass</td></tr>
<tr><td>ISO 18562-3 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)</td><td>Verify that the amount of Volatile substances are below the acceptance limit</td><td>The MOS (Margin Of Safety) value shall be higher than 1 for identified substances.</td><td>
<table>
<tr><th rowspan="2">Substance</th><th>MOS</th><th>MOS</th></tr>
<tr><th>Neonate</th><th>Pedriatic/ Adult</th></tr>
<tr><td>Cyclohexane</td><td>35.0</td><td>83.3</td></tr>
<tr><td>Ethylbenzene</td><td>7.8</td><td>32.5</td></tr>
<tr><td>m+p-Xylene</td><td>4.2</td><td>10.0</td></tr>
<tr><td>o-Xylene</td><td>15.0</td><td>35.7</td></tr>
<tr><td>Tetrachloroethylene</td><td>4.7</td><td>11.1</td></tr>
<tr><td>Trichlorofluoromethane</td><td>27.6</td><td>65.6</td></tr>
</table>

Pass</td></tr>
</table>

Conclusion:

The conclusions drawn from the clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K030071).