January 30, 2018

Maquet GmbH
Holger Ullrich
Director Product Compliance
Kehler Strasse 31
Rastatt, 76437 De

Re: K172159
Trade/Device Name: Getinge GSS67N Series Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: December 27, 2017
Received: December 28, 2017

Dear Holger Ullrich:

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.

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.

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,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172159

Device Name
Getinge GSS67N Series Steam Sterilizer

Indications for Use *(Describe)*
The Getinge GSS67N Series Steam Sterilizer is intended for use by health care facilities to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam. The GSS67N Series Steam Sterilizer is available in 3 models differentiated by chamber length; GSS67N Model 6710 (39 inch chamber), GSS67N Model 6713 (51 inch chamber) and GSS67N Model 6717 (67 inch chamber).

List of available cycles:
See table below

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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List of available cycles:

Getinge GSS67N Series Steam Sterilizer Cycles and Load Chart

Cycle Type	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Drying Time		6710 1000mm (39 in.)	6713 1300mm (51 in.)	6717 1700mm (67 in.)
PREVAC 1	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
PREVAC 2	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric Packs	18	24	30
PREVAC 4	132.2°C (270.0°F)	4 min	30 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
PREVAC 5	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
B & D TEST	134°C (273.0°F)	3 min, 30 sec	0 min	1 B&D Test Pack in an EMPTY chamber (other than loading accessories)	1 Test Pack	1 Test Pack	1 Test Pack
GRAVITY 1	121.1°C (250.0°F)	30 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 2	135.0°C (275.0°F)	10 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 3	132.2°C (270.0°F)	15 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
				Fabric packs	18	24	30
IUSS 1 Vac (Note 7)	135.0°C (275.0°F)	3 min	1 min (Note 4)	Instrument Tray (25lb)	1	1	1
				Single Instrument Tray	1	1	1

IUSS 2 Grav (Note 7)	135.0°C (275.0°F)	10 min	0.5 min (Note 4)	Instrument Tray (25lb)	1	1	1
				Single Instrument/Tray	1	1	1
IUSS 3 Grav (Note 7)	132.2°C (270.0°F)	4 min	1 min (Note 4)	Instrument Tray (25lb)	1	1	1
				Single Instrument/Tray	1	1	1
LIQUIDS	121.1°C (250.0°F)	45 min	3 kPa/min (0.44 psi/min) (Note 3)	Each container 1000 mL (34 fl oz) or smaller (Notes 5, 6)	3	3	3
LEAK TEST (Note 2)	131.1°C (268.0°F)	N/A	N/A	Empty Chamber (other than loading accessories)	_	_	_

NOTE: Liquid Cycles are not intended for the sterilization of liquids used for direct patient contact.

TABLE NOTES:

1. The load configurations listed in these tables are those used during testing validations of the sterilizer. These configurations follow *AAMI Standard ST8: Hospital steam sterilizers* where applicable (fabric packs are process challenge devices as described in ANSI/AAMI ST8 and were made to be consistent with the packs described in ANSI/AAMI ST8). For guidance on processing loads in the sterilizer, refer to *AAMI Standard ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.

2. Vacuum leak test parameters are not adjustable.

3. Cooldown rate

4. Items may NOT be dry at the end of the following cycles:
   - IUSS 1, 2, 3
   - PREVAC 2
   - PREVAC 5

   Drying time may be added if required.

5. Facility must validate the cycle if the load includes containers larger than 1000 mL (34 fl oz).

6. Use vented or open containers only.

7. The recommended minimum exposure time and temperature for unwrapped, nonporous loads (e.g., metal instruments) that are sterilized for immediate use is 3 minutes at 132°C (270°F) or 135°C (275°F).

K172159 510(k) SUMMARY

Getinge GSS67N Series Steam Sterilizer

Submitted by: Maquet GmbH
Kehler Strasse 31
Rastatt DE-BW
Germany 76437

Contact Person: Barb Smith, RAC
Sr. Regulatory Affairs Specialist
Phone: (585) 214-6049
Email: barb.smith@getinge.com

Date prepared: Jan 30, 2018

Proprietary Name: GSS67N Series Steam Sterilizer

Common Name: Steam Sterilizer

Device Classification: Steam Sterilizer (80 FLE)

Class II, as listed per 21 CFR 880.6880

Predicate Device: Getinge 633HC Series Steam Sterilizer [K070657]

Description of Device:

The Getinge GSS67N Series Steam Sterilizer is designed for sterilization of heat and moisture stable materials used in healthcare facilities. There are three model designations to identify three different chamber lengths. The model 6710 is 1000 mm (39”) long, model 6713 is 1300 mm (51”) long and model 6717 is 1700 mm (67”) long.

The Getinge GSS67N Series Steam Sterilizer employs both gravity/downward displacement with positive pulse conditioning and pressure/vacuum pulsing for dynamic air removal. Up to 11 standard cycles can be easily accessed and custom cycle names can be designated by the user. All cycle phases are sequenced and monitored by the control system, providing both audible and visual notification of deviation from certain operating parameters.

Intended Use:

The Getinge GSS67N Series Steam Sterilizer is intended for use by health care facilities to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam. The GSS67N Series Steam Sterilizer is available in 3 models differentiated by chamber length; GSS67N Model 6710 (39 inch chamber), GSS67N Model 6713 (51 inch chamber) and GSS67N Model 6717 (67 inch chamber).

List of available cycles:

Getinge GSS67N Series Steam Sterilizer Cycles and Load Chart

Cycle Type	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Drying Time		6710 1000mm (39 in.)	6713 1300mm (51 in.)	6717 1700mm (67 in.)
PREVAC 1	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
PREVAC 2	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric Packs	18	24	30
PREVAC 4	132.2°C (270.0°F)	4 min	30 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
PREVAC 5	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
B & D TEST	134°C (273.0°F)	3 min, 30 sec	0 min	1 B&D Test Pack in an EMPTY chamber (other than loading accessories)	1 Test Pack	1 Test Pack	1 Test Pack
GRAVITY 1	121.1°C (250.0°F)	30 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 2	135.0°C (275.0°F)	10 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 3	132.2°C (270.0°F)	15 min	45 min	Double-wrapped instrument trays, up to 11.3 kg (25.0 lb) (per tray)	8	12	16
				Fabric packs	18	24	30

IUSS 1 Vac (Note 7)	135.0°C (275.0°F)	3 min	1 min (Note 4)	Instrument Tray (25lb)	1	1	1
				Single Instrument Tray	1	1	1
IUSS 2 Grav (Note 7)	135.0°C (275.0°F)	10 min	0.5 min (Note 4)	Instrument Tray (25lb)	1	1	1
				Single Instrument/Tray	1	1	1
IUSS 3 Grav (Note 7)	132.2°C (270.0°F)	4 min	1 min (Note 4)	Instrument Tray (25lb)	1	1	1
				Single Instrument/Tray	1	1	1
LIQUIDS	121.1°C (250.0°F)	45 min	3 kPa/min (0.44 psi/min) (Note 3)	Each container 1000 mL (34 fl oz) or smaller (Notes 5, 6)	3	3	3
LEAK TEST (Note 2)	131.1°C (268.0°F)	N/A	N/A	Empty Chamber (other than loading accessories)	–	–	–

NOTE: Liquid Cycles are not intended for the sterilization of liquids used for direct patient contact.

TABLE NOTES:

1. The load configurations listed in these tables are those used during testing validations of the sterilizer. These configurations follow *AAMI Standard ST8: Hospital steam sterilizers* where applicable (fabric packs are process challenge devices as described in ANSI/AAMI ST8 and were made to be consistent with the packs described in ANSI/AAMI ST8). For guidance on processing loads in the sterilizer, refer to *AAMI Standard ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.

2. Vacuum leak test parameters are not adjustable.

3. Cooldown rate

4. Items may NOT be dry at the end of the following cycles:
   - IUSS 1, 2, 3
   - PREVAC 2
   - PREVAC 5

   Drying time may be added if required.

5. Facility must validate the cycle if the load includes containers larger than 1000 mL (34 fl oz).

6. Use vented or open containers only.

7. The recommended minimum exposure time and temperature for unwrapped, nonporous loads (e.g., metal instruments) that are sterilized for immediate use is 3 minutes at 132°C (270°F) or 135°C (275°F).

Comparisons to Predicate Device:

Similarities between the Getinge GSS67N Series Steam Sterilizer and the identified predicate device (Getinge 633HC Series Steam Sterilizer) are:

- Intended use is the same: Intended for use by health care facilities to sterilize wrapped and unwrapped, porous and nonporous heat and moisture stable items such as surgical instruments and linens by means of pressurized steam.

- Operating Principle is the same: Saturated steam is the sterilizing agent.

- Materials of construction are the same: Vessel material is Stainless Steel SA240. There is no direct patient contact associated with this device.

- Cycle Types: The cycle types offered are the same; Prevacuum, Gravity, Immediate Use (Flash) and Liquids (not for sterilization of liquids used directly for patient contact).

- Performance Testing: Factory recommended cycles were tested per industry standards and guidelines and effectiveness of sterilizer function was demonstrated by complete kill of biological indicators. Getinge Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8 Hospital Steam Sterilizers.

The differences between the Getinge GSS67N Series Steam Sterilizer and the predicate device (Getinge 633HC Series Steam Sterilizer) are:

- The Getinge GSS67N series provides standard cycles validated to the current AAMI ST8:2013 *Hospital Steam Sterilizers* standard and thus provides testing of instrument trays up to 25 lbs. In addition the GSS67N has included 132°C cycles that were not validated on the predicate device.

- The Getinge GSS67N Series Steam Sterilizer offers one larger vessel size than the 633HC Series.

- The Getinge GSS67N Series Steam Sterilizer removes air from the chamber by means of a vacuum pump as opposed to a water injector (used in 633HC predicate) thus allowing for less water usage.

- The Getinge GSS67N Series Steam Sterilizer has an updated touchscreen display.

Summary of Performance Testing:

Factory recommended cycles were tested per industry standards and guidelines and effectiveness of sterilizer function was demonstrated by complete kill of biological indicators. Getinge GSS67N Series Steam Sterilizers have been validated to meet the requirements of ANSI/AAMI ST8:2013 *Hospital Steam Sterilizers*.
The results of Getinge GSS67N Series Steam Sterilizer validation testing demonstrate that the sterilizer performs as intended. Summary of testing:

- Empty chamber testing performed for all cycles as described in ANSI/AAMI ST8:2013 *Hospital Steam Sterilizers* section 5.4.2.5. The results demonstrated that the sterilizer is capable of providing steady-state thermal conditions within the chamber that are consistent with the predicated sterility assurance level (SAL) in the load.

- All PREVAC and GRAVITY cycles were validated using fabric process challenge packs as described in ANSI/AAMI ST8:2013 section 5.5.2. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and moisture retention of less than 3% increase in pre-sterilization test pack weight including no visible wet spots.

- All PREVAC (excluding PREVAC 2 and PREVAC 5 that have shortened drying times) and GRAVITY cycles were validated using wrapped instrument process challenge devices as described in ANSI/AAMI ST8:2013 section 5.5.4. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and moisture retention of less than 20% increase in pre-sterilization weight of the towel including no visible wet spots on the outer wrapper.

- All Immediate Use (IUSS) cycles were validated using an unwrapped non-porous process challenge device as described in ANSI/AAMI ST8:2013 section 5.5.5. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12 and complete BI kill.

- Liquid loads cycles were validated using 3 one liter flasks as described in ANSI/AAMI ST8:2013 section 5.5.3. The results from this testing demonstrated a sterility assurance level of at least 10^{-6} through achievement of time at temperature sufficient to produce an Fo value of at least 12, complete BI kill and water loss not exceeding 50ml.

- Bowie Dick cycle was validated using the Bowie-Dick test pack as described in ANSI/AAMI ST8:2013 section 5.6.1.1.

- The software validation for the cycle operation was performed according to FDA guidance document "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*".

- The electrical safety and EMC testing was completed per IEC 61010-1 "Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1: General requirements" (IEC 61010-1:2010 (Third Edition) +A1:2016; IEC 6101-2-040 "Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-040, Particular requirements for sterilizers and washer-disinfectors used to treat medical materials; and IEC 61326:2013 "Electrical Equipment for Meassurement, Control and Laboratory Use - EMC requirements", Part 1: General Requirements".

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The GSS67N Series Steam Sterilizer meets the applicable requirements of AAMI ST8:2013 performance standards. The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device K070657.