May 18, 2022

Maquet GmbH
℅ Barb Smith
Sr. Regulatory Affairs Specialist
Getinge
45 Barbour Pond
Wayne, New Jersey 07470

Re: K214120
Trade/Device Name: GSS610N21 Series Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: April 13, 2022
Received: April 14, 2022

Dear Barb 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K214120

Device Name
Getinge GSS610N21 Steam Sterilizer

Indications for Use *(Describe)*

The Getinge GSS610N21 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.

Please see "GSS610N Load chart table" (1 page) as attachment to this form.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Getinge GSS610N21 Series Steam Sterilizer Cycles and Load Chart

Cycle Type	Factory Settings			Load Configuration (Note 1)	Maximum Items for Model 61021 [2100 mm or 82.7 in chamber length]
	Exp. Temp.	Exp. Time	Drying Time		
P1 PREVAC 1	135.0°C (275.0°F)	3 min	16 min	Full instrument packs	36
P2 PREVAC 2	135.0°C (275.0°F)	3 min	3 min	Full fabric packs	80
P3 PREVAC 4	132.2°C (270.0°F)	4 min	30 min	Full instrument packs	36
P4 PREVAC 5	132.2°C (270.0°F)	4 min	5 min	Full fabric packs	80
P5 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 B&D Test Pack
P6 GRAVITY 1	121.1°C (250.0°F)	30 min	45 min	Full instrument packs	36
				Full fabric packs	80
P7 GRAVITY 2	135.0°C (275.0°F)	10 min	45 min	Full instrument packs	36
				Full fabric packs	80
P8 GRAVITY 3	132.2°C (270.0°F)	15 min	45 min	Full instrument packs	36
				Full fabric packs	80
P9 IUSS 1 Vac	135.0°C (275.0°F)	3 min	1 min	Full instrument packs	1
P10 IUSS 2 Grav	135.0°C (270.0°F)	10 min	30 sec	Full instrument packs	1
P11 IUSS 3 Grav	132.2°C (270.0°F)	4 min	1 min	Full instrument packs	1
P12 Vented Bottles	121.1°C (250.0°F)	45 min	3kPa/min (0.44 psi/ min) (Note 2)	Each container 1000 mL (34 fl oz) or smaller (Note 3)	3

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. Cooldown rate

3. Use vented or open containers only.

510(k) Summary
Getinge GSS610N21 Series Steam Sterilizer
K214120

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

Contact person Barb Smith
Sr. Regulatory Affairs Specialist
Phone: 585-370-6101
Email: barb.smith@getinge.com

510(k) number K214120

Date Prepared December 22, 2021

Proprietary Device Name

Trade Name: Getinge GSS610N21 Series Steam Sterilizer

Models: 610N21 82.7 inch (2100 mm) long chamber
Common Name: Steam Sterilizer
Classification: Steam Sterilizer (21CFR880.6880, Product Code 80 FLE)

Predicate Devices

[K201927] Getinge GSS610N Series Steam Sterilizer Getinge Models 610N10, 610N14 and 610N15. SE Date 03/01/2021

Description of Device

The steam sterilizer is used 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 Getinge GSS610N21 Series Steam Sterilizer employs both gravity/downward displacement with positive pulse conditioning and pressure/vacuum pulsing for dynamic air removal. All cycle phases are sequenced and monitored by the control system, providing both audible and visual notification of deviation from certain operating parameters

Indications for Use

The Getinge GSS610N21 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.

Cycles and Load Chart

Getinge GSS610N21 Series Steam Sterilizer Cycles and Load Chart

Cycle Type	Factory Settings			Load Configuration (Note 1)	Maximum Items for Model 61021 [2100 mm or 82.7 in chamber length]
	Exp. Temp.	Exp. Time	Drying Time		
P1 PREVAC 1	135.0°C (275.0°F)	3 min	16 min	Full instrument packs	36
P2 PREVAC 2	135.0°C (275.0°F)	3 min	3 min	Full fabric packs	80
P3 PREVAC 4	132.2°C (270.0°F)	4 min	30 min	Full instrument packs	36
P4 PREVAC 5	132.2°C (270.0°F)	4 min	5 min	Full fabric packs	80
P5 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 B&D Test Pack
P6 GRAVITY 1	121.1°C (250.0°F)	30 min	45 min	Full instrument packs	36
				Full fabric packs	80
P7 GRAVITY 2	135.0°C (275.0°F)	10 min	45 min	Full instrument packs	36
				Full fabric packs	80
P8 GRAVITY 3	132.2°C (270.0°F)	15 min	45 min	Full instrument packs	36
				Full fabric packs	80

P9 IUSS 1 Vac	135.0°C (275.0°F)	3 min	1 min	Full instrument packs	1
P10 IUSS 2 Grav	135.0°C (270.0°F)	10 min	30 sec	Full instrument packs	1
P11 IUSS 3 Grav	132.2°C (270.0°F)	4 min	1 min	Full instrument packs	1
P12 Vented Bottles	121.1°C (250.0°F)	45 min	3kPa/min (0.44 psi/ min) (Note 2)	Each container 1000 mL (34 fl oz) or smaller (Note 3)	3

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 andwere 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. **Cooldown rate**

3. **Use vented or open containers only.**

Technological Characteristics Table:

Shown below is a comparison of the subject device Getinge GSS610N21 Series Steam Sterilizer versus the predicate device (Getinge GSS610N Series Steam Sterilizer models 610N10, 610N14, 610N15). The GSS610N21 sterilizer is the largest model in the GSS610N series of steam sterilizers:

Item	Getinge GSS610N [Predicate device] K201927	Getinge GSS610N21 [Subject Device]	Comparison
Pressure Vessel			
Chamber Sizes	Model 610N10: 26.4” x 42.5” x 40.9” (672 x1080 x1040 mm)	Model 610N21: 26.4” x 42.5” x 82.7” (672 x 1080 x 2100 mm)	Different Chamber Sizes
	Model 610N14: 26.4” x 42.5” x 55.1” (672 x1080 x1400 mm)		Different Chamber Sizes

Item	Getinge GSS610N [Predicate device] K201927	Getinge GSS610N21 [Subject Device]	Comparison
	Model 610N15: 26.4" x 42.5" x 60.6" (672 x1080 x1540 mm)		Different Chamber Sizes
Chamber Volumes	Model 610N10: Single Door 26.52 Cu Ft (751L), Double Door 26.59 Cu Ft (753L) Model 610N14: Single Door 35.73 Cu Ft (1012L), Double Door 35.77 Cu Ft (1013L) Model 610N15: Single Door 39.3 Cu Ft (1113L), Double Door 39.34 Cu Ft (1114L)	Model 610N21: Double Door 53.67 Cu Ft (1520L)	The chamber volumes correspond to the chamber sizes. Only double door configuration available for subject device.
ASME Pressure Vessel	All pressure vessels are built to ASME Sect. VIII, Div. 1	All pressure vessels are built to ASME Sect. VIII, Div. 1	Same
"U" Stamped Unfired Pressure Vessel)	Chamber: 45 psi Jacket: 45 psi	Chamber: 45 psi Jacket: 45 psi	Same
Material of Jacket	Stainless Steel (SA240-304)	Stainless Steel (SA240- 304)	Same
Material of Chamber	Stainless Steel (SA240-316L)	Stainless Steel (SA240-316L)	Same
Vacuum method	Vacuum pump standard.	Vacuum pump standard.	Same
Chamber Closure			
Door Operation	Horizontal opening/closing door design operated by an electrical motor.	Horizontal opening/closing door design operated by an electrical motor.	Same
Safety and Interlocks			
Door switch system/steam to chamber interlock	Electro-mechanical logic	Electro-mechanical logic	Same
Cycles			
Types of cycles offered	Prevac 132.2°C, 4 min; 135°C, 3 min, Gravity 121°C, 30 min; 135°C 10 min; 132.2° 15 min;	Prevac 132.2°C, 4 min; 135°C, 3 min, Gravity 121°C, 30 min; 135°C 10 min; 132.2° 15 min;	Same

Item	Getinge GSS610N [Predicate device] K201927	Getinge GSS610N21 [Subject Device]	Comparison
	IUSS 135°C, 3 min,; 135C, 10 min; 132.2°C 4 min Vented Bottles 121°C 45min. BD Test	IUSS 135°C, 3 min,; 135C, 10 min; 132.2°C 4 min Vented Bottles 121°C 45min. BD Test	
Maximum Load Capacities	Reference chart for maximum loads within GSS610N - up to 25lbs per tray	Reference chart for maximum loads within GSS610N21 - up to 25lbs per tray	Maximum load increases with larger chamber size
Utility Requirements			
Primary Electrical Connection	GSS610N are available for connection to: 208V 3ph 60Hz (Not GSS61015N with integrated electrical heated steam boiler) 460V 3ph 60Hz 480V 3ph 60Hz	Available for connection to: 208V 3ph 60Hz (Not GSS61021N with integrated electrical heated steam boiler) 460V 3ph 60Hz 480V 3ph 60Hz 600V 3ph 60Hz	Same Limited for Subject device due to dual boilers

Summary of Performance Testing

Shown below is a summary of the non-clinical testing that was performed with this device:

Test Performed	Device Description	Test Method	Acceptance Criteria	Results
Biological Performance Tests				
Sterilization Efficacy Validation Biological Performance with a fabric PCD	GSS610N21	AAMI ST8:2013 (R2018) §5.5.2	Sterility Assurance Level (SAL) 10^{-6}	Pass
Biological Performance with liquid loads	GSS610N21	AAMI ST8:2013 (R2018) §5.5.3	Sterility Assurance Level (SAL) 10^{-6}	Pass
Biological Performance with a wrapped instrument PCD	GSS610N21	AAMI ST8:2013 (R2018) §5.5.4	Sterility Assurance Level (SAL) 10^{-6}	Pass

Biological performance of immediate-use steam sterilization for single-wrapped or unwrapped nonporous items	GSS610N21	AAMI ST8:2013 (R2018) §5.5.5	Sterility Assurance Level (SAL) 10^6	Pass
Physical Performance Test				
Chamber Temperature Profile	GSS610N21	AAMI ST8:2013 (R2018) §5.4.2.5	+3°C (or +6°F) and -0°C (or -0°F) of the selected sterilization exposure temperature	Pass
Mechanical Air Removal Test	GSS610N21	AAMI ST8:2013 (R2018) §5.6.1	Load reaching exposuire temperature witin 10 secs Color change on BD chemical indicator sheet	Pass Pass
Air Leak Rate Test	GSS610N21	AAMI ST8:2013 (R2018) §5.6.2	Average leak rate of 1 mmHg (0.13 kPa) (0.019 psia) per minute or less over the measured time interval.	Pass
Moisture Retention Rest	GSS610N21	AAMI ST8:2013 (R2018) §5.7	< 3% increase in presterilization test pack weight for fabric pack & <20% increase for wrapped instrument pack	Pass

Conclusion:

The conclusions drawn from the nonclinical test demonstrates that the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device.