January 22, 2026

Maquet GMBH (a Getinge Group company)
% Barb Smith
Principal Regulatory Affairs Specialist
Getinge
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K252307
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 19, 2025
Received: December 19, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHEN A. ANISKO -S

Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.01.22 16:37:42 -05'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control 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: 0MB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252307

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 tables 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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Pre-vacuum cycles. (Dynamic air removal cycles)

Cycle Name	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Drying Time		6710 1000 mm 39.4 in	6713 1300 mm 51.2 in	6717 1700 mm 66.9 in
PREVAC 1 135°C	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 2 135°C	135.0°C 275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 3 135°C [1)]	135.0°C 275.0°F	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 4 132.2°C	132.2°C (270.0°F)	4 min	30 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 5 132.2°C	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
PREVAC 6 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 7 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 8 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 9 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 10 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 11 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 12 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 13 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 14 132.2°C [3)]	132.2°C (270.0°F)	4 min	30 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 15 132.2°C [4)]	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
PREVAC 16 132.2°C [4)]	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
Bowie Dick 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
IUSS 1 135°C	135.0°C (275.0°F)	3 min	1 min (Note 4)	Double-wrapped instrument trays (up to 25 lbs per tray)	1	1	1
				Fabric packs	1	1	1
Leak Test (Note 2)	131.1°C (268.0°F)	N/A	N/A	Empty Chamber (other than loading accessories)	–	–	–

[1)] The cycle is an identical copy of PREVAC 1.
[2)] The cycle is an identical copy of PREVAC 2.
[3)] The cycle is an identical copy of PREVAC 4.
[4)] The cycle is an identical copy of PREVAC 5.

Gravity displacement cycles

Cycle Name	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Drying Time		6710 1000 mm 39.4 in	6713 1300 mm 51.2 in	6717 1700 mm 66.9 in
GRAVITY 1 121.1°C	121.1°C (250.0°F)	30 min	45 min	Double-wrapped instrument trays (up to 25 lbs per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 2 135°C	135.0°C (275.0°F)	10 min	45 min	Double-wrapped instrument trays (up to 25 lbs per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 3 132.2°C	132.2°C (270.0°F)	15 min	45 min	Double-wrapped instrument trays (up to 25 lbs per tray)	8	12	16
				Fabric packs	18	24	30
IUSS 2 135°C (Note 7)	135.0°C (270.0°F)	10 min	30 sec (Note 4)	Double-wrapped instrument trays (up to 25 lbs per tray)	1	1	1
				Fabric packs	1	1	1
IUSS 3 132.2°C (Note 7)	132.2°C (270.0°F)	4 min	1 min (Note 4)	Double-wrapped instrument trays (up to 25 lbs per tray)	1	1	1
				Fabric packs	1	1	1

Liquid load cycles

Cycle Name	Factory Settings			Load Configuration	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Cooling Time		6710 1000 mm 39.4 in	6713 1300 mm 51.2 in	6717 1700 mm 66.9 in
Vented Bottles 121°C	121.1°C (250.0°F)	45 min	3kPa/min (0.44 psi/min) (Note 3)	Each container 1000 mL (34 fl oz) or smaller (Note 5 and 6)	3	3	3

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

Only the cycles described in the above tables are cleared for use in United States Health Care settings.

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).

K252307 510(k) SUMMARY

Getinge GSS67N Series Steam Sterilizer

Submitted by: Maquet GmbH
Kehler Strasse 31
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Germany 76437
+49 7222 932-0
Dr. Silke Avieny

Contact Person: Barb Smith
Principal Regulatory Affairs Specialist
Phone: (585) 370-6101
Email: barb.smith@getinge.com

Date prepared: January 20, 2026

Proprietary Name: GSS67N Series Steam Sterilizer

Common Name: Steam Sterilizer

Device Classification: Steam Sterilizer (FLE)

Class II, as listed per 21 CFR 880.6880

Predicate Device: Getinge GSS67N Series Steam Sterilizer [K172159]

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. 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 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 tables below

Pre-vacuum cycles. (Dynamic air removal cycles)

Cycle Name	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Drying Time		6710 1000 mm 39.4 in	6713 1300 mm 51.2 in	6717 1700 mm 66.9 in
PREVAC 1 135°C	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 2 135°C	135.0°C 275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 3 135°C [1)]	135.0°C 275.0°F	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 4 132.2°C	132.2°C (270.0°F)	4 min	30 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 5 132.2°C	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
PREVAC 6 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 7 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 8 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 9 135°C [1)]	135.0°C (275.0°F)	3 min	16 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 10 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 11 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 12 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 13 135°C [2)]	135.0°C (275.0°F)	3 min	3 min (Note 4)	Fabric packs	18	24	30
PREVAC 14 132.2°C [3)]	132.2°C (270.0°F)	4 min	30 min	Double-wrapped instrument trays (up to 25 lbs per tray)	12	16	24
PREVAC 15 132.2°C [4)]	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
PREVAC 16 132.2°C [4)]	132.2°C (270.0°F)	4 min	5 min (Note 4)	Fabric packs	18	24	30
Bowie Dick 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

IUSS 1 135°C	135.0°C (275.0°F)	3 min	1 min (Note 4)	Double-wrapped instrument trays (up to 25 lbs per tray)	1	1	1
				Fabric packs	1	1	1
Leak Test (Note 2)	131.1°C (268.0°F)	N/A	N/A	Empty Chamber (other than loading accessories)	–	–	–

[1)] The cycle is an identical copy of PREVAC 1.
[2)] The cycle is an identical copy of PREVAC 2.
[3)] The cycle is an identical copy of PREVAC 4.
[4)] The cycle is an identical copy of PREVAC 5.

Gravity displacement cycles

Cycle Name	Factory Settings			Load Configuration (Note 1)	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Drying Time		6710 1000 mm 39.4 in	6713 1300 mm 51.2 in	6717 1700 mm 66.9 in
GRAVITY 1 121.1°C	121.1°C (250.0°F)	30 min	45 min	Double-wrapped instrument trays (up to 25 lbs per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 2 135°C	135.0°C (275.0°F)	10 min	45 min	Double-wrapped instrument trays (up to 25 lbs per tray)	8	12	16
				Fabric packs	18	24	30
GRAVITY 3 132.2°C	132.2°C (270.0°F)	15 min	45 min	Double-wrapped instrument trays (up to 25 lbs per tray)	8	12	16
				Fabric packs	18	24	30
IUSS 2 135°C (Note 7)	135.0°C (270.0°F)	10 min	30 sec (Note 4)	Double-wrapped instrument trays (up to 25 lbs per tray)	1	1	1
				Fabric packs	1	1	1
IUSS 3 132.2°C (Note 7)	132.2°C (270.0°F)	4 min	1 min (Note 4)	Double-wrapped instrument trays (up to 25 lbs per tray)	1	1	1
				Fabric packs	1	1	1

Liquid load cycles

Cycle Name	Factory Settings			Load Configuration	Maximum Items per Chamber Length		
	Exp. Temp.	Exp. Time	Cooling Time		6710 1000 mm 39.4 in	6713 1300 mm 51.2 in	6717 1700 mm 66.9 in
Vented Bottles 121°C	121.1°C (250.0°F)	45 min	3kPa/min (0.44 psi/min) (Note 3)	Each container 1000 mL (34 fl oz) or smaller (Note 5 and 6)	3	3	3

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

Only the cycles described in the above tables are cleared for use in United States Health Care settings.

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 GSS67N Series Steam Sterilizer K172159) 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 and Liquids (not for sterilization of liquids used directly for patient contact).

- Performance Testing: Programmed factory set 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 GSS67N Series Steam Sterilizer K172159) are:

• The Getinge GSS67N series steam sterilizer has been tested to performance standards using an increased load capacity. The validated load capacity for the 132C and 135C PreVac cycles has been increased as noted in the table below:

Cycle	Load Configuration	6710	6713	6717
PreVac 1, 3, 6-9 135C	Double Wrapped Instrument Trays (up to 25lbs)	Increase from 8 to12	Increase from 12 to 16	Increase from 16 to 24
PreVac 4,14 132.2C	Double Wrapped Instrument Trays (up to 25lbs)	Increase from 8 to12	Increase from 12 to 16	Increase from 16 to 24

- The software and software documentation used in the GSS67N Series Steam Sterilizer has been updated to comply with FDA guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions and Content of Premarket Submissions for Device Software Functions.

Summary of Performance Testing:

Evaluation	**Standards Used**	**Results**
Performance	ANSI/AAMI ST8:2013/(R) 2018 Hospital Steam Sterilizers	Passed - Cycles PREVAC 1 and PREVAC 4 were evaluated for performance with increased load size and demonstrated compliance to the standard
Electrical Safety (ES)	ANSI/UL 61010-1 3rd Ed dated May 12 2012 with revision through July 19 2019	Passed – results demonstrated compliance to the standard
EMC and ES	IEC 61010-2-040:2020	Passed – results demonstrated compliance to the standard
EMC	IEC 61326-1 Edition 3.0 2020-10	Passed – provided GAP analysis testing to bridge the gaps in specific tests covered in IEC 60601-1-2 that are not in IEC 61326-1." Results demonstrated compliance to the applicable sections of the standard
EMC	IEC 61010-2-040:2020	Passed – the results demonstrated compliance to the standard
EMC	FCC 47 CFR 15 and ICES-001	Passed – the results demonstrated compliance to the standard
Cybersecurity	FDA guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions	Meets the requirements of the guidance
Software	FDA guidance: Content of Premarket Submissions for Device Software Functions	Meets the requirements of the guidance

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate device, the subject devices Getinge GSS67N Series Steam Sterilizer has been shown to be as safe, as effective, and to perform as well or better than the legally marketed predicate device GSS67N Series Steam Sterilizer (K172159).