October 15, 2024

SteriTec Products Mfg. (a Getinge Group Company)
% Barb Smith
Principal Regulatory Affairs Specialist
Getinge
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K242795
Trade/Device Name: Getinge Assured MI Steam Migrating Integrator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: September 16, 2024
Received: September 16, 2024

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: 2024.10.15 15:28:23 -04'00'

for: Christopher Dugard
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: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242795

Device Name
Getinge Assured MI Steam Migrating Integrator

Indications for Use *(Describe)*
The Getinge Assured MI Steam Migrating Integrator strip is an internal pack integrating indicator designed to react to critical process parameters of a steam sterilization cycle within a stated tolerance. The integrating indicator is intended to be placed in each pack, pouch, tray, or container to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:
250°F/121°C, 30 minutes Gravity
270°F/132°C, 10 minutes Dynamic Air Removal
270°F/132°C, 4 minutes Dynamic Air Removal
270°F/132°C, 15 minutes Gravity
273°F/134°C, 3 minutes Dynamic Air Removal
273°F/134°C, 4 minutes Dynamic Air Removal
275°F/135°C, 3 minutes Dynamic Air Removal
275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles Immediate Use Steam Sterilization (IUSS):
270°F/132°C, 4 minutes Dynamic Air Removal IUSS
270°F/132°C, 3 minutes Gravity IUSS
270°F/132°C, 10 minutes Gravity IUSS
275°F/135°C, 3 minutes Dynamic Air Removal IUSS
275°F/135°C, 3 minutes Gravity IUSS
275°F/135°C, 10 minutes Gravity IUSS

Stated values (as determined in a steam resistometer):
30 minutes at 121°C
9.1 minutes at 128°C
3.3 minutes at 132°C
2.4 minutes at 134°C
1.5 minutes at 135°C

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."

SteriTec Products, Inc.
74 Inverness Drive East
Englewood, CO 80112
(303) 660-4201

510(k) Summary
K242795

Date Prepared: October 15, 2024

Applicant Information

SteriTec Products Manufacturing CO INC
(a Getinge Group company)
74 Inverness Drive East
Englewood, CO 80112 U.S.
Ph: 303-660-4201

Contact: Barb Smith
Principal Regulatory Affairs Specialist
Ph: 585-370-6101
e-mail: barb.smith@getinge.com

1. Device Name

Trade Name: Getinge Assured MI Steam Migrating Integrator

Device Classification: Class II

Common/Usual Name: Indicator, physical/chemical sterilization process

Classification Name: Indicator, physical/chemical sterilization process (21 CFR 880.2800, JOJ)

2. Predicate Device

Getinge Assured MI Steam Migrating Integrator (K200252). SteriTec Products, Manufacturing Co. Inc.

3. Description of Device

The Getinge Assured MI Steam Migrating Integrator Strip is used in each pack to be sterilized to monitor exposure to critical process parameters of steam sterilization. The Getinge Assured MI meets the performance specifications for a Type 5 Integrating Indicator as defined by ANSI/AAMI/ISO 11140-1:2014.

It consists of a paper wick and a steam sensitive chemical pellet containing blue colored dye. A pellet is held within a pocket located at one end of an aluminum foil tape base. The foil tape base is adhered to a film material that has been bonded with a paper label. During steam sterilization, the Integrating Indicator pellet will melt and migrate into the PASS window when the specified critical parameters of steam sterilization have been met.

SteriTec Products, Inc.
74 Inverness Drive East
Englewood, CO 80112
(303) 660-4201

4. Intended Use/Indications for Use:

The Getinge Assured MI Steam Migrating Integrator strip is an internal pack integrating indicator designed to react to critical process parameters of a steam sterilization cycle within a stated tolerance. The integrating indicator is intended to be placed in each pack, pouch, tray, or container to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:

250°F/121°C, 30 minutes Gravity
270°F/132°C, 10 minutes Dynamic Air Removal
270°F/132°C, 4 minutes Dynamic Air Removal
270°F/132°C, 15 minutes Gravity
273°F/134°C, 3 minutes Dynamic Air Removal
273°F/134°C, 4 minutes Dynamic Air Removal
275°F/135°C, 3 minutes Dynamic Air Removal
275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles Immediate Use Steam Sterilization (IUSS):

270°F/132°C, 4 minutes Dynamic Air Removal IUSS
270°F/132°C, 3 minutes Gravity IUSS
270°F/132°C, 10 minutes Gravity IUSS
275°F/135°C, 3 minutes Dynamic Air Removal IUSS
275°F/135°C, 3 minutes Gravity IUSS
275°F/135°C, 10 minutes Gravity IUSS

Stated values (as determined in a steam resistometer):

30 minutes at 121°C
9.1 minutes at 128°C
3.3 minutes at 132°C
2.4 minutes at 134°C
1.5 minutes at 135°C

The intended use of the subject device has only been modified with the addition of sterilization cycles, from the referenced predicate device. The monitoring of the following cycles has been added:

- 10 minutes at 132°C Dynamic Air Removal
- 3 minutes at 134°C Dynamic Air Removal
- 4 minutes at 134°C Dynamic Air Removal.

5. Technological Characteristics

The chart below compares the technological characteristics of the subject device, to that of the predicate device:

SteriTec Products, Inc.
74 Inverness Drive East
Englewood, CO 80112
(303) 660-4201

Feature	Predicate Device (K200252)	Modified/Subject Device (K242795)	Comparison
Intended Use/Indications for Use	The Getinge Assured MI Steam Migrating Integrator strip is an internal pack integrating indicator designed to react to critical process parameters of a steam sterilization cycle within a stated tolerance. The integrating indicator is intended to be placed in each pack, pouch, tray, or container to function as an independent monitor of critical parameters for the following sterilization cycles: **Steam Sterilization Cycles:** • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal 275°F/135°C, 10 minutes Gravity **Steam Sterilization Cycles (IUSS):** • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 3 minutes Gravity • 270°F/132°C, 10 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity • 275°F/135°C, 10 minutes Gravity **Stated values (as determined in a steam resistometer):** • 30 minutes at 121°C • 9.1 minutes at 128°C • 3.3 minutes at 132°C • 1.5 minutes at 135°C	The Getinge Assured MI Steam Migrating Integrator strip is an internal pack integrating indicator designed to react to critical process parameters of a steam sterilization cycle within a stated tolerance. The integrating indicator is intended to be placed in each pack, pouch, tray, or container to function as an independent monitor of critical parameters for the following sterilization cycles: **Steam Sterilization Cycles:** • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 3 minutes Dynamic Air Removal • 273°F/134°C, 4 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 10 minutes Gravity **Steam Sterilization Cycles (IUSS):** • 270°F/132°C, 4 minutes Dynamic Air Removal IUSS • 270°F/132°C, 3 minutes Gravity IUSS • 270°F/132°C, 10 minutes Gravity IUSS • 275°F/135°C, 3 minutes Dynamic Air Removal IUSS • 275°F/135°C, 3 minutes Gravity IUSS • 275°F/135°C, 10 minutes Gravity IUSS **Stated values (as determined in a steam resistometer):** • 30 minutes at 121°C • 9.1 minutes at 128°C • 3.3 minutes at 132°C • 2.4 minutes at 134°C • 1.5 minutes at 135°C	The Intended Use of proposed modified device is the same. This submission proposes the monitoring of additional exposure temperatures and times: • 10 minutes at 132°C Dynamic Air Removal • 3 minutes at 134°C Dynamic Air Removal • 4 minutes at 134°C Dynamic Air Removal .
Device Design	A paper wick and a steam sensitive chemical pellet containing blue colored dye. A pellet is held within a pocket located at one end of an aluminum foil tape base. The foil tape base is adhered to a film material that has been bonded with a paper label. During steam sterilization, the integrating indicator pellet will melt and migrate into the PASS window when the specified critical parameters of steam	A paper wick and a steam sensitive chemical pellet containing blue colored dye. A pellet is held within a pocket located at one end of an aluminum foil tape base. The foil tape base is adhered to a film material that has been bonded with a paper label. During steam sterilization, the integrating indicator pellet will melt and migrate into the PASS window when the specified critical parameters of steam sterilization have been met.	Same

	sterilization have been met.		
Sterilization methods and cycles	**Steam Sterilization Cycles:** • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal 275°F/135°C, 10 minutes Gravity **Steam Sterilization Cycles (IUSS):** • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 3 minutes Gravity • 270°F/132°C, 10 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity • 275°F/135°C, 10 minutes Gravity	**Steam Sterilization Cycles:** • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 3 minutes Dynamic Air Removal • 273°F/134°C, 4 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 10 minutes Gravity **Steam Sterilization Cycles (IUSS):** • 270°F/132°C, 4 minutes Dynamic Air Removal IUSS • 270°F/132°C, 3 minutes Gravity IUSS • 270°F/132°C, 10 minutes Gravity IUSS • 275°F/135°C, 3 minutes Dynamic Air Removal IUSS • 275°F/135°C, 3 minutes Gravity IUSS • 275°F/135°C, 10 minutes Gravity IUSS	Same with the addition of cycles: • 10 minutes at 132°C Dynamic Air Removal • 3 minutes at 134°C Dynamic Air Removal • 4 minutes at 134°C Dynamic Air Removal
Indicator Agent	Proprietary	Proprietary	Same
Endpoint Specifications	The endpoint is determined by migration of the steam sensitive pellet, carrying the blue dye, to an area marked PASS on the indicator. Endpoint is reached at the stated value (SV) for each claimed temperature. Endpoint is not reached at the stated value – 15% time and/or 1°C.	The endpoint is determined by migration of the steam sensitive pellet, carrying the blue dye, to an area marked PASS on the indicator. Endpoint is reached at the stated value (SV) for each claimed temperature. Endpoint is not reached at the stated value – 15% time and/or 1°C.	Same
Shelf Life	5 Years	5 Years	Same

6. Non-Clinical Performance Testing

Performance testing was conducted to verify that the proposed Getinge Assured MI Steam Migrating Integrator meets the requirements for integrating indicators in accordance with the *Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators* for integrating indicators as well as *ANSI/AAMI/ISO 11140-1:2014*.

The following table summarizes the performance testing that was completed, with acceptance criteria and results to demonstrate that the Getinge Assured MI Steam Migrating Integrator met the requirements of its pre-determined acceptance criteria in its claimed intended steam sterilization cycles.

SteriTec Products, Inc.
74 Inverness Drive East
Englewood, CO 80112
(303) 660-4201

Performance Testing of 3 manufactured lots of Integrator	Pre-Determined Acceptance Criteria	Results
Steam Resistometer (BIER vessel) Testing: (According to ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements and Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff.)	Pass result at the stated value for each temperature claimed: - 30 Minutes at 121°C - 3.8 minutes at 132°C, 4.1 minutes at 132°C, 4.0 minutes at 132°C - 2.1 minutes at 134°C, 2.2 minutes at 134°C, 2.4 minutes at 134°C - 1.7 minutes at 135°C, 2.0 minutes at 135°C, 1.8 minutes at 135°C,	PASS
	Failing Result at 15% less time of SV for each temperature claimed	PASS
	Failing Result at 1°C less for each temperature claimed	PASS
Hospital Steam Sterilizer Testing: (To demonstrate pass/fail results from an actual sterilization cycle used in a health care facility according to Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff)	100% samples passing under passing conditions for each cycle	PASS
	100% samples failing under failing conditions for each cycle	PASS
Dry Heat Testing: (According to ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements and Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff)	Failing result when exposed to dry heat alone for 30 minutes (±1 minute) at 140°C (±2°C)	PASS
Side-by-side testing of the biological indicator and integrator in steam resistometer: (As specified in Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff)	The integrator does not reach its endpoint before the biological indicator is inactivated	PASS
Offset/Transference: (According to ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements.)	The indicator agent shall not offset or bleed, penetrate the substrate to which it is applied, or materials in which it is in contact before, during or after the sterilization cycles for which it is designed	PASS

SteriTec Products, Inc.
74 Inverness Drive East
Englewood, CO 80112
(303) 660-4201

7. Conclusion:

Based on the results from the performance testing per the Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators for integrating indicators as well as ANSI/AAMI/ISO 11140- 1:2014, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K200252), Class II Indicator, physical/chemical sterilization process (21 CFR 880.2800), JOJ.