May 21, 2020

SteriTec Products MFG Co Inc
Jonathan Rutigliano
Director, Regulatory Affairs
74 Inverness Drive East
Englewood, Colorado 80112

Re: K200252
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: February 21, 2020
Received: February 24, 2020

Dear Jonathan Rutigliano:

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,

CAPT Elizabeth Claverie, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200252

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, 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

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."

510(k) Summary

Manufacturing Facility
SteriTec Products Manufacturing CO INC
74 Inverness Drive East
Englewood, CO 80112
Ph: 303-660-4201

Contact: Jonathan Rutigliano
Director, Regulatory Affairs
Ph: 303-660-4201
e-mail: Jon.Rutigliano@Getinge.com

Submission Date: May 16, 2020

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

Steris Steam Integrating Indicator (K152630). Steris Corporation

3. Description of Device

The Getinge Assured MI Steam Migrating Integrator is a single use device to monitor steam sterilization cycles. The integrating indicator is 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 sterilization cycles. During steam sterilization, the integrating indicator pellet will migrate into the PASS zone when sterilization conditions have been met.

4. 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

5. Technological Characteristics

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

Feature	PREDICATE	510(k) Filing	COMPARISON

Intended Use	The integrating indicator is designed to chemically react over time with the critical parameters of steam sterilization cycles within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Steam Sterilization Cycles: • 250°F/121°C- 30 min 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	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	Similar

Device Design	Backing material with embossed cavity containing temperature sensitive chemical and coloring dye, wicking strip, covered with laminated paper containing labeling and windows.	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 base. The foil base is adhered to label material that has been bonded with a film. During steam sterilization, the integrating indicator pellet will migrate into the PASS zone when the specified critical parameters of steam sterilization have been met.	Similar
Sterilization methods and cycles	Steam Sterilization Cycles: • 250°F/121°C- 30 min 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, 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 IUSS • 270°F/132°C, 10 minutes Gravity IUSS • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity 275°F/135°C, 10 minutes Gravity	Same
Indicator Agent	Proprietary	Proprietary	Same

Endpoint Specifications	The endpoint is determined by migration of the steam sensitive dye to an area marked ACCEPT (OK) 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 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
Endpoint Stability	6 months	6 months	Same
Shelf Life	5 Years	5 Years	Same

6. Performance Testing

Performance testing was conducted to verity 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 the results demonstrate that the Getinge Assured MI Steam Migrating Integrator met the requirements of the pre-determined acceptance criteria in its claimed intended steam sterilization cycles.

Test Methodology	Purpose	Pre-Determined Acceptance Criteria	Results
Steam Resistometer (BIER vessel) Testing	To test the pass/fail criteria for each critical cycle parameter and provide the pass/fail results to show how the chemical integrator reacts to all the critical parameters in the sterilization cycle for which it is intended 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 - 3.3 minutes at 132°C - 1.5 minutes at 135°C	PASS
		Failing Result at 15% less time of SV for each temperature claimed	PASS

Steam Resistometer (BIER vessel) Testing	To evaluate one parameter at a time in a resistometer while holding the other parameters constant according to Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff	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	To demonstrate that the integrator does not change color following a dry heat cycle 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	To demonstrate that the chemical integrator parallels the performance of an appropriate biological indicator. The results of this study should demonstrate that the integrator does not reach its endpoint before the biological indicator is inactivated, 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	To demonstrate the indicator agent does not bleed or offset to substrate which it is applied 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

7. Conclusion

Based on the results from the performance testing as required in 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 proposed device is as safe, as effective and performs as well as or better than the legally marketed device (K152630), Class II Indicator, physical/chemical sterilization process (21 CFR 880.2800), JOJ.