February 20, 2025

SteriTec Products, Inc. (a Getinge Company)
% Barb Smith
Principal Regulatory Affairs Specialist
Getinge
75 Barbour Pond
Wayne, New Jersey 07470

Re: K250172
Trade/Device Name: Green Card Bowie-Dick Test (BD115)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: January 17, 2025
Received: January 21, 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,

Christopher K. Dugard -
S

Christopher K. Dugard, M.S.
Division 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.

Submission Number *(if known)*

K250172

Device Name

Green Card Bowie-Dick Test (BD115)

Indications for Use *(Describe)*

The Green Card Bowie-Dick Test is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 270°F (132°C) and 273°F (134°C) for 3.5 minutes. The indicator will demonstrate a uniform color change from purple to green when the proper sterilization conditions are met and no air is present. If enough air is present to create a 2°C or greater temperature difference in a standard Bowie-Dick test towel pack, the indicator will demonstrate a non-uniform color change.

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
K250172

Date Prepared: February 17, 2025

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: Green Card Bowie-Dick Test (BD115)

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

SteriTec Bowie-Dick Mini Pak (K024293). SteriTec Products, Manufacturing Co. Inc.

3. Description of Device

The Green Card Bowie-Dick Test is designed specifically for daily monitoring of pre-vacuum steam sterilizers to detect the presence of residual air as recommended by ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. The Green Card Bowie-Dick Test is a 3.5" X 1.91" card with the indicator ink printed on one side. Both sides of the card are laminated with a polyester film and an identification/record label is placed on the back side. The Green Card Bowie-Dick Test duplicates the resistance of a Bowie-Dick towel pack as described in ANSI/AAMI ST8 Hospital Steam Sterilizers.

The Green Card Bowie-Dick Test indicator areas will uniformly change color from purple to green when a passing Bowie-Dick test is performed. If a significant amount of air is present inside the sterilizer chamber during the sterilization cycle, it will be detected by the Green Card and

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

displayed as a purple area on the indicator card, whereas the remainder of the indicator will have turned green. The non-uniform color change demonstrates the presence of air that would have created a 2°C temperature depression in a standard cloth Bowie-Dick pack.

4. Intended Use/Indications for Use:

The Green Card Bowie-Dick Test Card is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 270°F (132°C) and 273°F (134°C) for 3.5 minutes.

The indicator will demonstrate a uniform color change from purple to green when the proper sterilization conditions are met, and no air is present. If enough air is present to create a 2°C or greater temperature difference in a standard Bowie-Dick test towel pack, the indicator will demonstrate a non-uniform color change.

5. Technological Characteristics

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

Feature	**Predicate Device** **SteriTec Bowie-Dick Mini Pak (K024293)**	**Subject/Modified Device** **Green Card Bowie-Dick Test**	**Comparison**
Intended Use/ Indications for Use	SteriTec Bowie-Dick Mini Pak is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 132° C for 3.5 minutes. The indicator will demonstrate a uniform color change from purple to green when the proper sterilization conditions are met, and no air is present. If enough air is present to create a 2° C or greater temperature difference in a standard Bowie-Dick test towel pack, the indicator will demonstrate a non-uniform color change.	The Green Card Bowie-Dick Test Card is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 270°F (132°C) and 273°F (134°C) for 3.5 minutes. The indicator will demonstrate a uniform color change from purple to green when the proper sterilization conditions are met, and no air is present. If enough air is present to create a 2°C or greater temperature difference in a standard Bowie-Dick test towel pack, the indicator will demonstrate a non-uniform color change.	The Intended Use of the modified device is the same as the predicate. This submission proposes the monitoring of an additional exposure temperature and time to the Indications for Use of: • 134°C 3.5 minutes In addition, the name was changed from Bowie-Dick Mini Pak to Green Card Bowie-Dick Test.
Device Design	Card measuring 3.5”x1.85” with indicator ink printed on one side and laminated with a polyester film on both sides. Identification/record label is on the back side opposite the indicator side. Indicator area will turn uniformly from purple to green when a	Card measuring 3.5”x1.91” with indicator ink printed on one side and laminated with a polyester film on both sides. Identification/record label is on the back side opposite the indicator side. Indicator area will turn uniformly from purple to green when a	Minor change in card dimension.

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

	successful Bowie-Dick test is performed. If a significant amount of air is present in the sterilizer chamber during the test, the indicator will have a non-uniform color change with purple still present. The card is placed inside a holder assembly prior to placement in the sterilizer. The holder is open on both sides allowing the unrestricted flow of steam and air removal around the card. The holder acts as a weight to keep the indicator card from blowing around during the test. The holder does not have any functionality regarding the test itself.	successful Bowie-Dick test is performed. If a significant amount of air is present in the sterilizer chamber during the test, the indicator will have a non-uniform color change with purple still present. The card is placed inside a holder assembly prior to placement in the sterilizer. The holder is open on both sides allowing the unrestricted flow of steam and air removal around the card. The holder acts as a weight to keep the indicator card from blowing around during the test. The holder does not have any functionality regarding the test itself.	
Sterilization methods and cycles	Steam sterilizer Bowie-Dick test 132°C 3.5 minutes	Steam sterilizer Bowie-Dick test 132°C 3.5 minutes and 134°C 3.5 minutes	This submission proposes the monitoring of additional exposure temperature and time to the Indications for Use of: • 134°C 3.5 minutes
Indicator Agent	Proprietary	Proprietary	Same
Color Change	The indicator area will change from purple to green when exposed to steam sterilization cycle with acceptable vacuum cycles.	The indicator area will change from purple to green when exposed to steam sterilization cycle with acceptable vacuum cycles.	Same
Interpretation	If no significant amount of residual air is present, the indicator will show a uniform green color change. If the indicator shows a purple color in the center, this indicates the presence of residual air.	If no significant amount of residual air is present, the indicator will show a uniform green color change. If the indicator shows a purple color in the center, this indicates the presence of residual air.	Same
Shelf Life	2 Years	2 Years	Same

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

6. Non-Clinical Performance Testing

Performance testing was conducted to verify that the proposed Green Card Bowie-Dick Test meets the applicable portions of ANSI/AAMI/ISO 11140-5 Sterilization of health care products — Chemical indicators Part 5: Class 2 indicators for Bowie and Dick-type air removal tests.

The following table summarizes the performance testing that was completed, with acceptance criteria and results to demonstrate that performance of the Green Card Bowie-Dick Test is as safe and effective as the predicate device. This testing confirms and demonstrates that the proposed device meets the requirements of its pre-determined acceptance criteria in its claimed intended steam sterilization cycles.

Performance Testing of 3 manufactured lots of Green Card Bowie-Dick Test	Pre-Determined Acceptance Criteria	Results
Uniform Color Change (Pass Test)-ANSI/AAMI/ISO 11140-5 Annex B	The Standard Test Pack must demonstrate no greater than a 0.5° C difference between the inside of the Standard Test Pack and the drain temperature and shall remain so for the duration of the exposure time exclusive of a 15 second equilibration time. This should be demonstrated with a thermocouple graph. The SteriTec Green Card Bowie-Dick Test Card indicator cards must demonstrate a uniform color change to green	PASS
Non-Uniform Color Change (Fail Test)- ANSI/AAMI/ISO 11140-5 Annex F	The Standard Test Pack must demonstrate a 2° C (+1°/-0°C) temperature difference between the towel pack and the drain temperatures for the last one minute of the three and half minute sterilization cycle. This should be demonstrated with a thermocouple graph. The SteriTec Green Card Bowie-Dick Test Card indicator cards must demonstrate a non-uniform color change with a purple area in the center and the rest of the indicator green.	PASS
Dry Heat Testing - ANSI/AAMI/ISO 11140-5 Annex C	The SteriTec Green Card Bowie-Dick Test Card shall show either no change or a change that is markedly different from the change occurring after exposure to a steam sterilization process.	PASS
Color Density Test- ANSI/AAMI/ISO 11140-5 Annex A	Difference in color density between the substrate and indicator should be not less than 0.3.	PASS
Indicator Color Stability	Verify that the Green Card Indicator sample end color has not changed to any other color and has remained green after 18 months or longer from steam sterilization exposure.	PASS

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

	Verify that the Green Card Indicator sample fail point color has not changed to any other color and has remained purple in center of card after 18 months or longer from steam sterilization exposure.	
Shelf-Life Stability	The following tests will be performed at 24 months of shelf life or longer. • The pass cycle samples shall exhibit complete color change to green. • The fail cycle samples shall exhibit incomplete color change. This presents as a purple spot in the center of the test card.	PASS

7. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device in 510(k) submission K250172, the modified Green Card Bowie-Dick Test, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared in K024293, Class II Indicator, physical/chemical sterilization process (21 CFR 880.2800), JOJ.