April 22, 2026

SteriTec Products
% Barb Smith
Principal Regulatory Affairs Specialist
Getinge
45 Barbour Pond Drive
Wayne, New Jersey 07470

Re: K252306
Trade/Device Name: Verrix EVA™ STEAM Biological Indicator (BI) (Model: 1200)
Verrix EVA™ STEAM Process Challenge Device (PCD) (Model: 1300)
combined with Verrix EVA™ Auto-Reader (Model: 1100)
Regulation Number: 21 CFR 880.2806
Regulation Name: Biological Sterilization Indicator With Indirect Growth Detection
Regulatory Class: Class II
Product Code: QVB
Dated: July 23, 2025
Received: July 24, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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: 2026.04.22 13:50:12 -04'00'

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

510(k) Number *(if known)*
K252306

Device Name
Verrix EVA™ STEAM Biological Indicator (BI) (Model: 1200)
Verrix EVA™ STEAM Process Challenge Device (PCD) (Model: 1300) combined with Verrix EVA™ Auto-Reader (Model: 1100)

Indications for Use *(Describe)*

The Verrix EVA™ STEAM Biological Indicator (BI) 1200 in conjunction with the Verrix EVA™ Auto-reader 1100 is intended for routine monitoring of the steam sterilization process for the following cycles:

• 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles
• 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization cycles

When used in conjunction with the Verrix EVA™ Auto-reader 1100, the Verrix EVA™ STEAM Biological Indicator 1200 provides a sterilization confirmation result within 7 minutes.

The Verrix EVA™ STEAM Biological Indicator (BI) 1200 is not recommended and should not be used for qualification testing purposes.

The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 in conjunction with the Verrix EVA™ Auto-reader 1100 is intended for routine monitoring of the following sterilization cycles:

• 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles
• 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization cycles

When used in conjunction with the Verrix EVA™ Auto-Reader 1100, the Verrix EVA™ STEAM Biological Indicator 1200 contained in the PCD provides a sterilization confirmation result within 7 minutes.

The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 is not recommended and should not be used for qualification testing purposes.

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.

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510(k) Summary
K252306

Date Prepared: April 21, 2026

Applicant Information

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Contact: Barb Smith
Principal Regulatory Affairs Specialist
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1. Device Name

Trade Name: Verrix EVA™ STEAM Biological Indicator (BI) (Model: 1200)

Verrix EVA™ STEAM Process Challenge Device (PCD) (Model: 1300) combined with Verrix EVA™ Auto-Reader (Model: 1100)

Common/Usual Name: Sterilization Biological Indicator

Device Classification: Class II, 21CFR 880.2806

Product Code: QVB

Classification Name: Biological Sterilization Indicator with Indirect Growth Detection

2. Predicate Device

Terragene® Bionova® Photon Biological Indicator (BT225),

Terragene Bionova Photon Auto-Reader Incubator (BPH) (DEN220042)

Reference Device: Terragene® Bionova® PCD (PCD225-C) (K242453)

3. Description of Device

The Verrix EVA™ STEAM Biological Indicator (BI) is a single-use device containing a spore carrier inoculated with a defined minimum number of *Geobacillus stearothermophilus* and a germinant reservoir in a self-contained polypropylene enclosure. The Verrix EVA™ STEAM BI used in conjunction with the Verrix EVA™ Auto-reader provides a way to verify the

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effectiveness of STEAM sterilization cycles. The Verrix EVA™ STEAM BI packaged in an appropriate process challenge device is placed in the steam sterilizer cycle to be challenged. After the sterilization cycle, the BI is removed and processed in the Verrix EVA Auto-Reader.

The Verrix EVA™ STEAM Process Challenge Device (PCD) contains a Verrix EVA™ STEAM Biological Indicator (BI) and a steam sterilization chemical integrator. The Verrix EVA™ STEAM PCD is placed in the steam sterilizer cycle to be challenged. After the sterilization cycle, the BI is removed from the PCD and processed in the Verrix EVA Auto-Reader.

The Verrix EVA™ Auto-Reader (Model: 1100) automatically activates the BI, saturating the spore carrier with germinant. The spores are incubated and exposed to a UV light source. When triggered by the germinant, viable spores will germinate and release dipicolinic acid (DPA). The detection of the DPA released by germinating spores is an indication of sterilization failure. The Auto-reader signals a positive result if germination is detected or a negative result if no germination is detected within the sterilization confirmation cycle time. The Verrix EVA™ Auto-reader is designed to automatically activate, incubate and analyze Verrix EVA™ STEAM Biological Indicators (BIs) and provide a final biological result within 7 minutes.

Note: Getinge intends to market the device under the name Getinge Assure TruSpore Biological Indicator System.

4. Intended Use/Indications for Use:

The Verrix EVA™ STEAM Biological Indicator (BI) 1200 in conjunction with the Verrix EVA™ Auto-reader 1100 is intended for routine monitoring of the steam sterilization process for the following cycles:

- 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles
- 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization cycles

When used in conjunction with the Verrix EVA™ Auto-reader 1100, the Verrix EVA™ STEAM Biological Indicator 1200 provides a sterilization confirmation result within 7 minutes.

The Verrix EVA™ STEAM Biological Indicator (BI) 1200 is not recommended and should not be used for qualification testing purposes.

The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 in conjunction with the Verrix EVA™ Auto-reader 1100 is intended for routine monitoring of the following sterilization cycles:

- 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles
- 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization cycles

When used in conjunction with the Verrix EVA™ Auto-Reader 1100, the Verrix EVA™ STEAM Biological Indicator 1200 contained in the PCD provides a sterilization confirmation result within 7 minutes.

The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 is not recommended and should not be used for qualification testing purposes.

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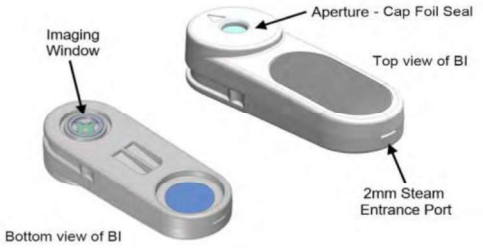
5. Technological Characteristics

The tables below compare the technological characteristics of the subject device, to that of the predicate device:

Predicate Device - Terragene Bionova Photon BI DEN220042; Terragene Bionovo Photon Auto-Reader Incubator (BPH)	**Subject Device –** Verrix EVA™ STEAM Biological Indicator (BI) 1200; Verrix EVA™ STEAM Process Challenge Device (PCD) 1300; Verrix EVA™ Auto-Reader 1100	**Difference**
		Design of the self-contained biological indicator is different. Both designs meet the requirements in recognized standards, guidance documents and special controls.
Fluorescence of exogenous sensor protein combined with a fluorophore in the media indicating if the sterilization cycle has disrupted the protein structure. Fluorescence readout is an indirect measure of the viability of Geobacillus stearothermophilus spores after the sterilization process (positive result).	Ultraviolet light picks up release of dipicolinic acid (DPA) from germinating spores indicating survival/viability. Indirect measurement of spore growth.	Methods of action for reading processed BI are different. Both designs meet the requirements established under special controls for product code QVB through the predicate devices DeNovo DEN220042.

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	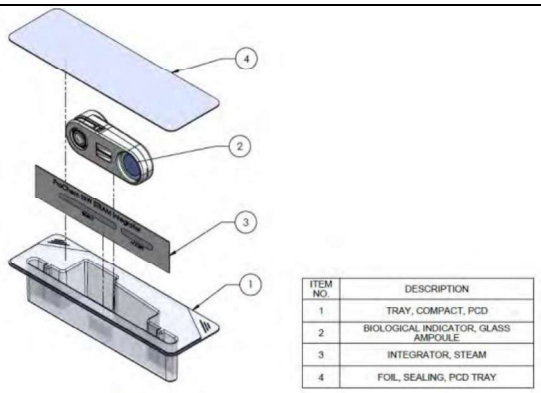 ITEM NO. / DESCRIPTION 1 TRAY, COMPACT, PCD 2 BIOLOGICAL INDICATOR, GLASS AMPOULE 3 INTEGRATOR, STEAM 4 FOIL, SEALING, PCD TRAY	PCD designs are different, but both meet the test standard of equivalency to the AAMI 16-towel test pack.

Feature	**Predicate Device Terragene Bionova Photon BI DEN220042**	**Submission Device Verrix EVA™ STEAM Biological Indicator (BI) 1200**	**Comparison**
Indications for Use	The Terragene Bionova Photon Biological Indicator (BT225); Terragene Bionova Photon Auto-Reader Incubator (BPH) is indicated as follows: Terragene® Bionova® Photon Biological Indicator (BT225) is a 7-second readout Self-Contained Biological Indicator (SCBI) inoculated with a minimum of 10^6 viable Geobacillus stearothermophilus bacterial spores and is intended for routine monitoring of the efficacy of steam sterilization	The Verrix EVA™ STEAM Biological Indicator (BI) 1200 in conjunction with the Verrix EVA™ Auto-reader 1100 is intended to monitor the steam sterilization process for the following cycles o 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles o 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization	Intended use is the same – monitoring of steam sterilization. Verrix EVA is not labeled for use in Gravity-displacement steam cycles (predicate is). Indications for use is for: 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles and 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization cycles – same for both predicate and subject device.

	processes. BT225 SCBI is not recommended and should not be used for qualification testing purposes. On each Terragene® Bionova® SCBI is a chemical process indicator that changes color from pink to brown when exposed to steam. Gravity-displacement Steam Sterilization Cycles - 132 ºC, 25 minutes - 132 ºC, 15 minutes -132 ºC, 10 minutes -135 ºC, 10 minutes Dynamic-air-removal Steam Sterilization Cycles 132 ºC, 4 minutes 135 ºC, 3 minutes Terragene® Bionova® Photon Auto-reader Incubator (BPH) incubates at 60 °C and reads the Terragene® Bionova® Photon SCBIs at the times prescribed in the User Manual.	cycles When used in conjunction with the Verrix EVA™ Auto-reader 1100, the Verrix EVA™ STEAM Biological Indicator 1200 provides a sterilization confirmation result within 7 minutes. The Verrix EVA™ STEAM Biological Indicator (BI) 1200 is not recommended and should not be used for qualification testing purposes. The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 in conjunction with the Verrix EVA™ Auto-reader 1100 is intended to qualify and monitor the following sterilization cycles: o 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles o 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization cycles	This submission includes the Verrix Process Challenge Device (PCD) using Terragene predicate referenced in K242453

		When used in conjunction with the Verrix EVA™ Auto-Reader 1100, the Verrix EVA™ STEAM Biological Indicator 1200 contained in the PCD provides a sterilization confirmation result within 7 minutes. The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 is not recommended and should not be used for qualification testing purposes.	
Indicator Organism	Geobacillus stearothermophilus	Geobacillus stearothermophilus	Same
Mechanism of Action	Upon the SCBI activation (the ampoule contained in the SCBI is crushed), the culture medium soaks the carrier and the fluorophore (contained in the media) comes into contact with the spores (and outer exogenous proteins). In non-sterilized SCBIs or after unsuccessfully sterilization processes, the fluorophore molecules bind to the hydrophobic cavities in structurally intact spore-associated proteins, significantly increasing its	When the SCBI is activated (ampoule is crushed) the germinant media soaks into the spore carrier and any surviving G. stearothermophilus spores release dipicolinic acid (DPA) through the germination process within minutes. An ultraviolet light source, operating at 275 nm with an output power of 100 mW embedded in the EVA Auto-reader will illuminate any germination-released DPA in the biological indicator. The charge coupled device will selectively	Methods of action for reading processed BI are different. Both designs meet the requirements established under special controls for product code QVB through the predicate devices DeNovo DEN220042.

	fluorescence signal, detected by the Auto-reader. The presence of fluorescence upon incubation in the Auto-reader indicates a sterilization process failure. Optionally, a visual color change confirmation can be performed.	detect and report on individual germinated G. stearothermophilus spores based on DPA-induced changes in pixel intensity in the viewing area.	
Auto-Reader	Terragene Bionovo Photon Auto-Reader Incubator (BPH)	Verrix EVA™ Auto-Reader 1100	Same function - to provide readout of biological indicator.
Viable Spore Population	≥ 10^6 spores per carrier	≥ 10^5 spores per carrier	Different but both meet minimum acceptable criteria for the sterilization cycles they are indicated for use in.
Resistance	D-value: not less than 1.5 minutes at 121°C not less than 10 seconds at 132°C not less than 8 seconds at 134°C	D-value: • ≥ 10 seconds at 132°C • ≥ 8 seconds at 135°C	Same at indicated cycle temps
Z-Value	Not less than 10°C	≥ 10°C	Same
Survival Time	Survival time = (log10 labeled population - 2) x labeled D-value	132°C ≥ 3.4 minutes 135°C ≥ 2.8 minutes Meets the longer of FDA and ISO 11138-1 and ISO 11138-3 requirements	Both meet ISO 11138-1 and ISO 11138-3 requirements
Kill Time	Kill time = (log10 labeled population + 4) x labeled D-value	132°C ≤ 9.9 minutes 135°C ≤ 8.5 minutes Meets the ISO 11138-1 and ISO 11138-3 requirements	Both meet ISO 11138-1 and ISO 11138-3 requirements
Carrier Material	Filter paper, 0.7 mm diameter	Black Polyester filter membrane, with a pore size 0.3 µm.	Different material used, but differences in design do not raise any issues of safety and effectiveness.

Incubation Temperature	60 ± 2 °C	60 ± 2 °C	Identical
Readout Time	7 seconds	7 minutes	Different readout times do not raise any issues of safety and effectiveness.
Chemical Indicator	Type 1 according to ISO 11140-1:2014 standard on label that changes from pink to brown when exposed to steam	Type 1 according to ISO 11140-1:2014 standard on BI housing that changes from blue to pink when exposed to steam	Same standard compliance with different ink color changes to indicate steam exposure.
Shelflife	18 months from manufacture	9 months from manufacture	Different shelflife claims do not raise any issues of safety and effectiveness.
FDA Regulation	880.2806 Product Code QVB	880.2806 Product Code QVB	same
Feature	**Predicate Device Terragene Bionovo Photon Auto-Reader Incubator (BPH)**	**Submission Device Verrix EVA™ Auto-Reader 1100**	**Comparison**
Indications for Use	Terragene® Bionova® Photon Auto-reader Incubator (BPH) incubates at 60 °C and reads the Terragene® Bionova® Photon SCBIs at the times prescribed in the User Manual.	The Verrix EVA™ Auto-Reader is designed to automatically activate, incubate, and analyze Verrix EVA™ STEAM Biological Indicators (BIs) and provide a final biological result within 7 minutes.	Same but specific to BI
Basis of Readout	Fluorescence of exogenous sensor protein combined with a fluorophore in the media indicating if the sterilization cycle has disrupted the protein structure.	Ultraviolet light picks up release of dipicolinic acid (DPA) from germinating spores indicating survival/viability. Indirect measurement of spore growth.	Methods of action for reading processed BI are different. Both designs meet the requirements established under special controls for product code QVB through the predicate devices DeNovo DEN220042.

Incubation Temperature Range	60 ± 2 °C	60 ± 2 °C	Same
Voltage Range	100-240 V AC	100-240 V AC	Same
Test Capacity	2 readout positions	4 readout positions	Verrix reader/incubator has more wells
Calibration	Auto-test upon start up	Self-calibrating; process positive control each day of use to verify functionality	Similar design intent and outcome
Incubation Time	7 seconds	7 minutes	Different readout times
Fluorescence Detection	Exogenous sensor protein combines with fluorophore and reader measures fluorescence intensity by means of an integrated sensor; increased fluorescence intensity indicates successful sterilizer cycle; based on sufficiently disrupting the structure of the exogenous protein and allowing activity with fluorophore.	UV illumination of dipliconic acid (DPA) released from spore germination activity	Methods of action for reading processed BI are different. Both designs meet the requirements established under special controls for product code QVB through the predicate devices DeNovo DEN220042.
Indication of Results	Green light = negative Red light = positive	Green light = negative (no germination) Red light = positive (germination detected)	Same green light/ red light concept
System Operation	The reader/incubator wells are arranged two total vertically and preset to 59°C. The user crushes the SCBI ampule using the crusher provided prior to placing in the incubator. Unit runs auto-test prior to being ready for use. User places BI in	The reader/incubator wells are arranged 4 across and preset to 59°C. The user opens and inserts a BI into an available well. The user closes the door until it clicks and the reader performs a visualization check to confirm the spore visualization window	Similar. The technical differences specified have been assessed to not raise any new questions of safety or effectiveness.

	reader well. When a positive result is detected in a reading position, the Position status indicator will turn red and an audible alarm will activate. When a negative result is detected in a reading position, the Position status indicator will turn green. Once the SCBI is removed, the green light, red light and audible alarm will turn off automatically after 30 seconds.	of the BI is in the Auto-reader field of view. Once visualization is confirmed, the system will automatically activate the biological indicator and begin the processing cycle. A countdown timer will appear in the corresponding bay status indicator on the LCD display until a final result is displayed. A negative result is indicated by a green light below the bay door and a green status indicator with a "-" symbol corresponding to the bay number on the LCD display. A negative result will be indicated if no organism is detected after a 7-minute process time A positive result is indicated by a red light below the bay door and a red status indicator with a "+" symbol corresponding to the bay number on the LCD display. A positive result will be indicated as soon as an organism is detected.	

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Feature	**Reference Device Terragene® Bionova® PCD (PCD225-C) K242453**	**Submission Device Verrix EVA™ STEAM Process Challenge Device (PCD) 1300**	**Comparison**
Indications for Use	Terragene® Bionova® Photon Process Challenge Device with Unique point integrator (PCD2252) and Bionova® Photon Process Challenge Device with moving front integrator (PCD225C) provide a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the ANSI/AAMI 16 towel pack. The devices are intended for routine monitoring of the following steam sterilization processes: Dynamic air removal 132°C 4 minutes Dynamic air removal 135°C 3 minutes Gravity displacement 132°C 25, 15, and 10 minutes Gravity displacement 135°C 10 minutes Terragene® Bionova® Photon Autoreader Incubator (BPH) incubates at 60°C and reads the Terragene® Bionova®Photon Biological Indicator (BT225) which is a 7second readout Self-	The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 provides a defined challenge resistance against the claimed cycles shown below and demonstrated resistance equivalence to the AAMI/ANSI 16 towel pack. The device provides routine monitoring of steam sterilization processes.: • 270ºF (132ºC) 4 minutes dynamic-air-removal (Pre-Vac) steam sterilization cycles • 275ºF (135ºC) 3 minutes dynamic-air-removal (Pre-Vac) steam sterilization cycles When used in conjunction with the Verrix EVA™ Auto-Reader 1100, the Verrix EVA™ STEAM Biological Indicator 1200 contained in the PCD provides a sterilization confirmation result	Intended use is the same – monitoring of steam sterilization. Indications for use is for: 270ºF (132ºC) 4 minutes dynamic air removal (Pre-Vac) steam sterilization cycles and 275ºF (135ºC) 3 minutes dynamic air removal (Pre-Vac) steam sterilization cycles – same for both predicate and subject device. The predicate is labeled for use in gravity-displacement steam cycles while the subject device is not, but this is not a significant difference between the products as the testing requirements remain the same, and the difference in labeled use raises no inherent questions of safety or effectiveness.

	Contained Biological Indicator (SCBI) inoculated with a minimum of 10^6 viable *Geobacillus stearothermophilus* bacterial spores.	within 7 minutes. The Verrix EVA™ STEAM Process Challenge Device (PCD) 1300 is not recommended and should not be used for qualification testing purposes.	
General Design	Bionova® PCD225-C consists of a disposable pre-assembled package as outlined in ANSI/AAMI ST79 which contains a BT225 Self-Contained Biological Indicator (SCBI), a PCDBI-C-RC Record Card and an IT26-C moving front chemical integrator (Type 5 according to ISO 11140-1:2014 standard) that gives instant visible indication that sterilizing conditions have been reached. Each pack consists of a stack of porous cards holding a SCBI tube that contains a population of Geobacillus stearothermophilus ATCC 7953 spores soaked on a carrier as well as growth indicator medium contained in a glass ampoule. Each SCBI has a process indicator (Type 1	Verrix EVA™ STEAM Process Challenge Device (PCD) contains a Verrix EVA™ STEAM Biological Indicator (BI) and a steam sterilization chemical integrator. One (1) Verrix EVA™ STEAM Biological Indicator and one (1) ProChem SSW Steam Sterilization Integrator are placed inside the polypropylene PCD Tray. The PCD Tray and sealing foil are sealed together to create the steam barrier for the components inside. The PCD Tray has a steam entrance port with 0.9mm in diameter at one end of the PCD Tray to control steam access for the Verrix EVA™ STEAM BI and the ProChem SSW Steam Sterilization Integrator inside the PCD Tray. The Verrix EVA™ STEAM Process Challenge Device	Design is different but both are designed to resistance equivalent to or greater than the AAMI 16-Towel Process Challenge Device (PCD) described in ANSI/AAMI ST79:2017.

	according to ISO 11140-1:2014 standard) on label that changes from pink to brown when exposed to steam. The moving front chemical integrator shows ACCEPT result when sterilization conditions were reached while process indicator (Type 1 according to ISO 11140-1:2014 standard) on PCD box changes from light blue to dark grey/black when exposed to steam.	(PCD) is designed to resistance equivalent to or greater than the AAMI 16-Towel Process Challenge Device (PCD) described in ANSI/AAMI ST79:2017.	
Biological Indicator	BT225 Self-Contained Biological Indicator (SCBI)	Verrix EVA™ STEAM Biological Indicator (BI) (model: 1200)	Different BI used
BI Incubation Temperature	60 ± 2 °C	60 ± 2 °C	same
BI Readout Time	7 seconds	7 minutes	Readout times are different
Resistance Comparison to the AAMI ST79 16 Towel PCD	Equivalent	Equivalent	same
Chemical Integrator	IT26-C moving front chemical integrator (Type 5 according to ISO 11140-1:2014 standard	ProChem SSW Steam Sterilization Integrator (K152630)	Different integrator used but both designed to Type 5 according to ISO 11140-1:2014 standard
External Process Indicator	Type 1 according to ISO 11140-1:2014 standard) on PCD box changes from light blue to dark grey/black when exposed to steam.	N/A – steam integrator is visible through clear PCD, an external indicator is not necessary	Verrix PCD does not require an external indicator as internal integrator is visible.
Shelf-life	18 months from the date of manufacture	9 months from date of manufacture	Different shelf-life claims do not raise any issues of safety and effectiveness.

Accessories	Terragene® Bionova® Photon Autoreader Incubator (BPH)	Verrix EVA™ Auto-Reader (Auto-Reader, or Reader) (model: 1100)	Reader/incubator specific to BI

6. Non-Clinical Performance Testing

Performance testing was conducted to verify that the proposed Verrix EVA™ STEAM Biological Indicator (BI) (Model: 1200) and Verrix EVA™ STEAM Process Challenge Device (PCD) (Model: 1300) combined with Verrix EVA™ Auto-Reader (Model: 1100) meets the applicable portions of Guidance for Industry and FDA Staff, Biological Indicator Premarket Notification [510(k)] Submissions, October 4, 2007, ISO 11138-1:2017 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements and ISO 11138-3:2017 Sterilization of health care products – Biological indicators - Part 3: Biological indicators for moist heat sterilization processes.

The following tables summarizes the performance testing that was completed, with acceptance criteria and results to demonstrate that the Verrix EVA™ STEAM Biological Indicator (BI) (Model: 1200) and Verrix EVA™ STEAM Process Challenge Device (PCD) (Model: 1300) combined with Verrix EVA™ Auto-Reader (Model: 1100) is safe and effective and performs equivalent to 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.

Table 1 Biological Indicator

Test Performed	Applicable Standard	Purpose	Acceptance Criteria	Results
Positive Control Test	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138- 3:2017	To evaluate performance of BI without steam exposure	All BIs must be EVA positive at 7 minutes	PASS
D-value for Steam 132ºC and Steam 135ºC cycles	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138- 3:2017	To evaluate the resistance characteristics of the BI	Steam 132ºC D-value - Minimum: 10 sec Steam 135ºC D-value - Minimum: 8 sec	PASS
Survival for Steam 132ºC and Steam 135ºC cycles	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138- 3:2017		Survival Time at 132ºC - Minimum: 1 min Survival Time at 135ºC - Minimum: 40 sec	PASS
Kill for Steam 132ºC and Steam 135ºC cycles	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138- 3:2017		Meets the requirements for Calculated kill time*	PASS

			* ISO 11138-1:2017	
Analytical and mechanistic validation.	FDA regulation 21 CFR 880.2806 (Biological sterilization indicator with indirect growth detection)	To demonstrate the relationship between the detected signal and the number of surviving spores	Provide testing under conditions near the pass/fail boundary (e.g., partial-kill conditions such as approximately 5–6 D values, where justified) and demonstrate a clear, predictable, and reproducible relationship between signal and survival outcomes under well-controlled conditions	PASS
Holding Time Assessment for Steam 132ºC and Steam 135ºC cycles	FDA Guidance[1], ISO 11138-1:2017 and ISO 11138- 3:2017	To evaluate the effect of the labeled holding time on the D-value	D-value must be within +/- 20% of the initial D-value calculated per ISO 11138- 1:2017	PASS
Simulated Use	FDA Guidance[1]	Verification of performance in claimed cycles	BI performs as intended in claimed cycles	PASS

1. FDA Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007

Table 2 PCD

Test Performed	**Applicable Standard**	**Purpose**	**Acceptance Criteria**	**Results**
Resistance of the Verrix EVA™ STEAM Process Challenge Device (PCD) as compared to AAMI 16 Towel PCD in claimed cycles	ANSI/AAMI ST79 and FDA Guidance document[1]	To evaluate the Challenge Pack as compared to the AAMI 16 Towel PCD in claimed cycles	Challenge Pack demonstrates equivalent resistance as compared to the AAMI 16 Towel PCD in claimed cycles	PASS

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Resistance of the Verrix EVA™ STEAM Process Challenge Device (PCD) as compared to the Biological Indicator and the Chemical Integrator alone in claimed cycles	FDA Guidance document[1]	To evaluate the Verrix EVA™ STEAM Process Challenge Device (PCD) as compared to the Biological Indicator itself and the Chemical Integrator alone in claimed cycles	Challenge Pack provides a greater challenge than Biological Indicator and Chemical Integrator itself in claimed cycles	PASS

1 Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007

7. Conclusion:

The conclusions drawn from the nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.