December 28, 2020

True Indicating LLC
Thomas Riha
CSO
946 Kane St
Toledo, Ohio 43612

Re: K200970
Trade/Device Name: True Indicating Self-Contained Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: December 02, 2020
Received: December 02, 2020

Dear Thomas Riha:

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,

Clarence W. Murray III, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200970

Device Name
True Indicating Self-Contained Biological Indicator

Indications for Use *(Describe)*
The True Indicating Self-Contained Biological Indicator is intended for monitoring the efficacy of saturated steam sterilization processes. The True Indicating Self-Contained Biological Indicator has a validated reduced incubation time of 10 hours and may be used in the following steam sterilization cycles:

121°C, 30 minutes (Gravity)
132°C, 4 minutes (Pre-Vacuum)
135°C, 3 minutes (Pre-Vacuum)

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 K200970

Submitter:	True Indicating LLC 946 Kane Street Suite A Toledo, OH 43612 P: 419 476 7119 F: 419 470 8899 E: info@trueindicating.com
Contacts:	Julie Wheeler President and Chief Operations Officer P:419 304 6535 F: 419 470 8899 julie.wheeler@trueindicating.com Tom Riha Chief Scientific Officer P: 248-982-6492 F: 419 470 8899 E: tom.riha@trueindicating.com
Prepared on:	December 28, 2020
Device Name:	True Indicating Self-Contained Biological Indicator
Classification:	21 CFR 880.2800, Class II Medical Device, FDA Product Code FRC, General Hospital
Predicate Devices: (Legally Marketed)	SporView® 10 Steam Self Contained Biological Indicator (K122024)
Device Description:	The True Indicating Self-Contained Biological Indicator (SCBI) consists of a 6 - mm filter paper disc inoculated with *Geobacillus stearothermophilus* ATCC® 7953, at a minimum of 10^5 bacterial spores encased within a polypropylene cap, and a polypropylene vial which includes a glass ampule hermetically sealed containing a nutrient broth culture medium modified with a pH indicator, Bromocresol Purple.
Indications for Use:	The True Indicating Self Contained Biological Indicator is Intended for monitoring the efficacy of saturated steam sterilization processes. The True Indicating Self-Contained Biological Indicator has a validated reduced incubation time of 10 hours and may be used in the following steam sterilization cycles: 121°C, 30 minutes (Gravity), 132°C, 4 minutes (Pre-Vacuum), and 135°C, 3 minutes (Pre-Vacuum).
Operational Principles:	Place an SCBI in the most difficult area to sterilize in a load. When the cycle is complete, the SCBI is retrieved and activated by crushing the growth medium ampule to engulf the disc within the bottom of the SCBI vial. The activated SCBI should be incubated at 55-65°C for a minimum of 10 hours. The SCBI should be monitored for visible signs of growth. Growth is indicated by a visual shift in color of the growth medium from purple to yellow, and/or the presence of turbidity. The absence of growth, resulting in growth medium remaining purple in color and/or no turbidity being visually present, indicates the cycle was effective.

Technological Characteristic Comparison Table

Feature	Subject Device True Indicating SCBI for Steam (K200970)	Predicate Device SporView® 10 Steam Self Contained Biological Indicator (K122024)	Comparison
Intended Use: Method of Sterilization	121°C, 30 minutes (Gravity) 132°C, 4 minutes (Pre-Vac) 135°C, 3 minutes (Pre-Vac)	Gravity 121°C 30 minutes Gravity 132°C 15 minutes Gravity 134°C 4 minutes Gravity-Flash 132°C 3 minutes Gravity-Flash 132°C 10 minutes Dynamic Air 121°C 20 minutes DynamicAir 121°C 30 minutes Dynamic Air 132°C 3 minutes Dynamic Air 132°C 4 minutes Dynamic Air 134°C 4 minutes Dynamic Air 135°C 3 minutes	Same
Product Code	FRC	FRC	Same
FDA Regulation	21 CFR§ 880.2800	21 CFR§ 880.2800	Same
Indications for Use (IFU)	The True Indicating Self-Contained Biological Indicator is intended for monitoring the efficacy of saturated steam sterilization processes. The True Indicating Self-Contained Biological Indicator has a validated reduced incubation time of 10 hours and may be used in the following steam sterilization cycles: 121°C, 30 minutes (Gravity) 132°C, 4 minutes (Pre-Vacuum) 135°C, 3 minutes (Pre-Vacuum)	SporView® 10 Steam is a self-contained biological indicator inoculated with viable Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of saturated steam sterilization processes. SporView® 10 self-contained biological indicators have a validated reduced incubation time of 10 hours and may be used in the following steam sterilization cycles: Gravity 121°C 30 minutes Gravity 132°C 15 minutes Gravity 134°C 4 minutes Gravity-Flash 132°C 3 minutes Gravity-Flash 132°C 10 minutes Dynamic Air 121°C 20 minutes DynamicAir 121°C 30 minutes Dynamic Air 132°C 3 minutes Dynamic Air 132°C 4 minutes Dynamic Air 134°C 4 minutes Dynamic Air 135°C 3 minutes	Same
Organism	*Geobacillus stearothermophilus* ATCC 7953	*Geobacillus stearothermophilus* ATCC 7953	Same
Mechanism of Action	Biochemical activity of *Geobacillus stearothermophilus* produces acid by-products that lower the pH of the media changing its color from purple to yellow	Biochemical activity of *Geobacillus stearothermophilus* produces acid by-products that lower the pH of the media which changing its color from purple to yellow	Same

Feature	**Subject Device True Indicating SCBI for Steam**	**Predicate SporView® 10 Steam Self Contained Biological Indicator (K122024)**	**Comparison**
Device Design	Inoculated paper disc and glass ampule with growth media contained within a vial and enclosed with a cap with liner	Inoculated paper disc and glass ampule with growth media contained within a vial and enclosed with a cap with liner	Same
Growth Medium Color Change	Purple to Yellow	Purple to Yellow	Same
Viable Spore Population	$\geq 10^5$ or greater	$\geq 10^5$ or greater	Same
Carrier Material	Paper Filter Carrier	Paper Filter Carrier	Same
Incubation Conditions	55 - 65 °C	55 - 60°C	Same
SCBI Label	Film label with Lot Number and expiration date	Film label with Lot Number and expiration date and chemical indicator that transitions from blue to dark	Similar
D value	D121 ≥ 1.5 min D132 ≥ 10 s D135 ≥ 8 s	D121 ≥ 1.5 min D132 ≥ 10 s D135 ≥ 8 s	Same
Reduced Incubation Time	10 hours	10 hours	Same
Hold Time	72 Hours	48 Hours	Similar
z value	≥ 10°C	≥ 10°C	Same
Shelf Life	24 Months	24 Months	Same

Summary of Nonclinical Testing: Per FDA recognized consensus standards and guidance documents testing was performed for steam sterilization processes using multiple lots of True Indicating SCBI for Steam over the range of the shelf life:

- Total Viable Spore Count was evaluated per manufacturer's methodology and in compliance with ISO 11138-1 Annex A

- Resistance Characteristic Studies were conducted including D value per ISO 11138-1 Annex D and ISO 11138-3 Annex A z value per ISO 11138-3 Annex B, and Survival/Kill Windows per ISO 11138-1 Annex E
- Carrier and Primary Packaging Materials were evaluated per Annex B and ISO 11138-3 7.1
- Hold Time Assessment was evaluated for a period of 72-hours per Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [510(k)] Submissions Section 7.D. Holding Time Assessment
- and True Indicating Protocol
- Reduced Incubation Time Studies were conducted per Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [51-(k)] Submissions Section 7.E. and Attachment II and True Indicating standard operating procedure
- Simulated Use – Full, Half, and Abbreviated Exposure Cycles were tested per Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [51-(k)] Submissions Section 7 and True Indicating Protocols

Summary of Nonclinical Testing Table:

Testing was conducted on the Test Pack following the FDA guidance and the standards below:

- 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
- ISO 11138-3:2017 Sterilization of health care products – Biological indicators, Part 3: Biological indicators for moist heat sterilization processes

Name of Test	Purpose	Acceptance Criterial	Subject Device Result
Viable Spore Population	Determine the spore population per the manufacturer's procedure following ISO 11138-1	$\geq 10^5$ or greater	**PASS** 1.0 – 4.8 x 10^5 Spore/SCBI
D value	Determine the resistance of the BI following ISO 11138-1 and 11138-3	D121 ≥ 1.5 min D132 ≥ 10 s D135 ≥ 8 s	**PASS** D121 ≥ 1.7 min D132 ≥ 18 s D135 ≥ 12 s
z value	Determine the z-value of the BI per ISO 11138-1 and 11138-3	≥10	**PASS** ≥11.6
Survival Time	Determine the exposure time for all BI's to retain viable spores (Survival Time) per ISO 11138-1, 11138-3 and Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Meets the longer of FDA and ISO 11138-3 requirements	**PASS** 121°C ≥ 5.9 min 132°C ≥ 1.1 min 135°C ≥ 42 sec
Kill Time	Determine the exposure time for all BI's to inactivate all spores (Kill Time) per ISO 11138-1,11138-3 and Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Meets the shorter of FDA and ISO 11138-3 requirements	**PASS** 121°C ≤ 28.0 min 132°C ≤ 2.8 min 135°C ≤ 1.8 min

Name of Test	Purpose	Acceptance Criterial	Subject Device Result
Reduced Incubation Time (RIT)	Determine the Reduced Incubation Time outlined in Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Meets FDA's requirement of > 97% alignment of the 10 hour results with the conventional incubation time of 7 days	**PASS** Minimum of 10 Hours
Carrier growth inhibition / media growth promotion	Determine the carrier growth inhibition/media growth promotion per ISO 11138-1 and 11138-3	Positive growth of less than 100 spores after primary packaging and media are subject to worst case steam exposure	**PASS**
Hold Time	Determine the length of time that an exposed BI can be held before incubation (Hold Time) per Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Performance not affected if incubated within 72 hours of exposure to steam sterilization	**PASS**
Simulated Use	Determine the simulated use of the BI in a sterilizer per Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Demonstrate growth when exposed to abbreviated cycle, all kill in a full cycle and a half cycle. All cycles utilized full loads using porous, non-porous, and mixed load material	**PASS** Abbreviated cycle – growth Half cycle – no growth Full cycle – no growth

Conclusion: Based on the non-clinical performance data, The True Indicating Self-Contained Biological Indicator is as safe, as effective, and performs as well as or better than the legally marketed predicate, SporView® 10 Steam Self Contained Biological Indicator cleared under K122024, Class II (21 CFR 880.2800), product code FRC.