December 14, 2021

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

Re: K210481
Trade/Device Name: Instant 20s Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: MTC
Dated: November 8, 2021
Received: November 8, 2021

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, PhD
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)*
K210481

Device Name
Instant 20s Indicator

Indications for Use *(Describe)*
The True Indicating Instant 20s Indicator, a multiple, interactive, bacterial enzyme indicator, is used for monitoring saturated steam sterilization processes operating at:

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.

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K210481 **510(k) Summary**

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Prepared on: December 13, 2021

Device Name: Instant 20s Indicator

Classification: Class II Medical Device, FDA Product Code MTC, General Hospital

Predicate Devices: (Legally Marketed) Sportrol Rapid Sterility Indicator, K962649

Description of Device: The True Indicating Instant 20s Indicator consists of a polycarbonate vial, polypropylene cap, a silicone vented cap which serves as a base, a vinyl sealant, and a biological tablet produced using cellulose, and enzymes from *Geobacillus stearothermophilus* ATCC® 7953.

Indications for Use: The True Indicating Instant 20s Indicator, a multiple, interactive, bacterial enzyme indicator, is used for monitoring saturated steam sterilization processes operating at: 121°C, 30 minutes (Gravity), 132°C, 4 minutes (Pre- Vacuum), 135°C, 3 minutes (Pre-Vacuum).

Operational Principles:

Place an Instant 20s Indicator in the most difficult area to sterilize in a load. When the cycle is complete, the Instant 20s Indicator is removed and the base is detached to gain access to the biological tablet. The Indicator Solution supplied with the Instant 20s Indicator is applied dropwise onto the biological tablet to activate.

The activated Instant 20s Indicator should be immediately viewed for a minimum of 20 seconds to determine the efficacy of the sterilization cycle. Ineffective cycles are indicated by a color shift of the biological tablet from off-white to a shade of red. The absence of a red color change indicates the cycle was effective. After 20 seconds, verify the color of the activated biological tablet and immediately discard the tablet.

Technological Characteristic Comparison Table

Feature	Subject Device Instant 20s Indicator (K210481)	Predicate Sportrol Rapid Sterility Indicator (K962649)	Comparison
Intended Use: Method of Sterilization	121°C, 30 minutes (Gravity) 132°C, 4 minutes (Pre-Vac) 135°C, 3 minutes (Pre-Vac)	121°C (Gravity) no stated time 132°C (Pre-Vac) no stated time 134°C (Pre-Vac) no stated time	Similar
Product Code	MTC	MTC	Same
FDA Regulation	21 CFR§ 880.2800	21 CFR§ 880.2800	Same
Indications for Use (IFU)	The True Indicating Instant 20s Indicator, a multiple, interactive, bacterial enzyme indicator, is used for monitoring saturated steam sterilization processes operating at: 121°C, 30 minutes (Gravity), 132°C, 4 minutes (Pre-Vacuum), 135°C, 3 minutes (Pre-Vacuum)	The RSI Rapid Indicator, a multiple, interactive, bacterial enzyme indicator, is used for monitoring saturated steam sterilization processes operating at 121°C gravity, 132°C vacuum assisted, 134°C vacuum assisted cycles.	Similar
Mechanism of Action	Enzymes, from *Geobacillus stearothermophilus*, react with Indicator Solution which consist of co-enzymes. The co-enzymes react with viable enzymes present in the tablet to produce a visual color change	Enzymes, from *Geobacillus stearothermophilus*, react with Indicator Solution which consist of co-enzymes. The co-enzymes can react with viable enzymes present in the tablet to produce a visual color change	Same
Modified Survival Time	121°C for 5 minutes 132°C for 20 seconds Calculated = 121°C, $\geq$ 5.1 min Calculated = 132°C, $\geq$ 1.0 min Calculated = 135°C, $\geq$ 40 sec Color change of Tablet was observed in response to enzymatic activity following the provided time points at the indicated temperatures.	121°C for 5 minutes 132°C for 20 seconds Calculated = Not Applicable	Similar

Feature	Subject Device Instant 20s Indicator for Steam (K210481)	Predicate Sportrol Rapid Sterility Indicator (K962649)	Comparison
Modified Kill Time	121°C for 15 minutes 132°C for 3 minutes Calculated = 121°C, ≤ 15.3 min Calculated = 132°C, ≤ 1.8 min Calculated = 135°C, ≤ 1.35 min Color change of Tablet was observed in response to enzymatic activity following the provided time points at the indicated temperatures	121°C for 15 minutes 132°C for 3 minutes Calculated = Not Applicable	Similar
Vial Label	Film label with Lot Number and Expiration Date	Paper label with Lot Number and expiration date and chemical indicator that transitions from Violet to Green	Similar
Shelf Life	Tablet = 13 Months Indicator Solution = 13 months	Tablet = 12 Months Indicator Solution = 12 Months	Similar
End Point Stability of Positive Result Color	7 Days	Not Applicable	Similar
End Point Stability of Negative Result Color	30 minutes	Not Applicable	Similar

Summary of Nonclinical Tests: Per FDA recognized consensus standards and guidance documents, testing was performed for steam sterilization processes using multiple lots of True Indicating Instant 20s Indicator over the range of the shelf life:

- 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
- 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
- Simulated Use – Full, Half, and Abbreviated Exposure Cycles were tested per Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [510(k)] Submissions Section 7 and True Indicating Protocols
- Chemical Indicator Performance per ISO 11140-1:2014 and FDA Staff Chemical Indicator (CI) Premarket Notification [510(k)] Submissions
- Biocompatibility (in Vitro Cytotoxicity) per ISO 10993-5:2009

Summary of Nonclinical Testing – Instant 20s Indicator

Testing was conducted on the Instant 20s Indicator following the FDA guidance and standards below:

- Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions, October 4, 2007
- Guidance for Industry and FDA Staff, Premarket Notification [510(k)] Submissions for Chemical indicators, December 19, 2003
- 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
- United Sates Pharmacopeia, <55> Biological Indicators – Resistance Performance Tests
- ISO 11140-1:2014 Sterilization of healthcare products – Chemical indicators - Part 1: General requirements
- ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

Summary of Nonclinical Testing Table

Name of Test	Purpose and Guidance Document/Standard	Acceptance Criteria	Subject Device Result
D value Based on Enzymatic Activity	Determine the resistance of the Instant 20s Indicator following ISO 11138-1 and 11138-3	D121 ≥ 1.5 min D132 ≥ 10 s D135 ≥ 8 s	**PASS** D121 ≥ 1.7 min D132 ≥ 12 s D135 ≥ 12 s
z value Based on Enzymatic Activity	Determine the z-value of the Instant 20s Indicator per ISO 11138-1 and 11138-3	≥10	**PASS** ≥13.6
Survival Time Based on Enzymatic Activity	Determine the exposure time for all Instant 20s Indicator 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 ≥ 5.1 min 132°C ≥ 1.0 min 135°C ≥ 40 sec
Kill Time Based on Enzymatic Activity	Determine the exposure time for all Instant 20s Indicator 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 ≤ 15.3 min 132°C ≤ 1.8 min 135°C ≤ 1.8 min

Hold Time	Determine the length of time that an exposed Instant 20s Indicator 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 used within 72 hours of exposure to steam sterilization	**PASS**
Growth Inhibition	Determine if positive result is achieved when primary packaging is subject to worst case steam exposure per Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	100% Positive Results	**Pass**
Shelf Life	Resistance and Survival/Kill must meet above criteria at each stability time point per ISO 11138-1, 11138-3 and Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	D value = see above Survival = see above Kill = see above	**PASS**
Chemical Indicator Performance	Determine the pass/fail criteria for each critical cycle parameter and provide the pass/fail results to show how the chemical indicator 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 Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Chemical Indicators	Pass result at Stated Value for each temperature claimed: 121°C, 30 minutes (Gravity) 132°C, 3 minutes (Pre-Vac) 135°C, 3 minutes (Pre-Vac)	**PASS**
		Fail Result at 15% less time and -1°C of Stated Value	**PASS**
Endpoint Stability of Positive Result Color	Determine the endpoint stability of developed color due to a positive result (failure) per Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Chemical Indicators	7 Days	**PASS**

Endpoint Stability of Negative Result Color	Determine the endpoint stability of color due to a negative result (pass) per Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Chemical Indicators	30 Minutes	**PASS**
Simulated Use	Determine the simulated use of the Instant 20s Indicator in a sterilizer per Guidance for Industry and FDA Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Demonstrates a survival (positive) result when exposed to abbreviated cycle, and all kill (negative) in full and half cycles	**PASS** Abbreviated cycles – positive Half cycles – negative Full cycles – negative

Name of Test	Purpose	Acceptance Criteria	Subject Device Result
Biocompatibility (In Vitro Cytotoxicity)	To determine if the device is cytotoxic to mammalian cells in vitro	Under conditions of the study, did not show potential toxicity to L-929 cells.	**PASS**

Conclusion: The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K210481, Instant 20s Indicator, is as safe, as effective, and performs as well or better than the legally marketed predicate device cleared under K962649.