June 18, 2026

True Indicating, LLC
Thomas Riha
Chief Scientific Officer
946 Kane St.
Toledo, Ohio 43551

Re: K251559
Trade/Device Name: InstaTRU Instant Biological Indicator for Steam (IBI-05)
Regulation Number: 21 CFR 880.2806
Regulation Name: Biological Sterilization Indicator With Indirect Growth Detection
Regulatory Class: Class II
Product Code: QVB
Dated: June 17, 2026
Received: June 17, 2026

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 (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: 2026.06.18 16:29:14 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control Devices
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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)*
K251559

Device Name
InstaTRU Instant Biological Indicator for Steam (IBI-05)

Indications for Use *(Describe)*
The True Indicating Instant Biological Indicator for Steam (IBI-05) is a biological indicator inoculated with a minimum of 10^5 viable Geobacillus stearothermophilus bacterial spores and is intended for routine monitoring of the efficacy of steam sterilization processes, and for monitoring processed loads, providing visual confirmation in 20 seconds. The IBI-05 is not recommended and should not be used for qualification testing purposes.

Gravity-displacement Steam Sterilization Cycles:
121 ºC for 30 minutes, 132 ºC for 25 minutes, 132 ºC for 15 minutes, 132 ºC for 10 minutes, and 132 ºC for 3 minutes.

Dynamic-air-removal Steam Sterilization Cycles:
132 ºC for 4 minutes and 135 ºC for 3 minutes.

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
K251559

Submitter: True Indicating LLC
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Prepared on: June 18th, 2026

Device Name: InstaTRU™ Instant Biological Indicator for Steam (IBI-05)

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

Predicate Devices: (Legally Marketed) Terragene Bionova Photon Biological Indicator (BT225) (DEN220042)

Description of Device: The True Indicating InstaTRU™ Instant Biological Indicator for Steam (IBI-05) consists of a polypropylene vial and a polypropylene cap. Attached on the outer bottom of the polypropylene vial is a vented cap, a foam plug made of polyester compressed into the cap used to delay steam penetration to a biological tablet, and a biological tablet produced using microcrystalline cellulose and *Geobacillus stearothermophilus* ATCC® 7953 with a minimum of 10^5 bacterial spores along with the enzymes naturally present within the organism, glucose dehydrogenase and diaphorase, which when combined together with the spores provide the result for determining if viable spores are present within 20 seconds of adding Indicator Solution.

Every set of IBIs includes a bottle of Indicator Solution which is required for determining the 20 second sterilization results of the IBI-05 for Steam.

The InstaTRU™ Instant Biological Indicator for Steam (IBI-05) also includes an optional Self-Contained Biological Indicator (SCBI) cleared under K200970 with a 6mm filter paper disc inoculated with *Geobacillus stearothermophilus* ATCC® 7953, $\geq 10^5$ bacterial spores encased within the polypropylene vial and includes a glass ampule hermetically sealed containing Soybean Casein Digest Broth (SCDB) growth medium modified with a pH indicator (bromocresol purple) which can be incubated to 55-65 degrees C to determine the outgrowth of the spores within 10 hours.

Indications for Use: The True Indicating Instant Biological Indicator for Steam (IBI-05) is a Biological Indicator inoculated with a minimum of 10^5 viable *Geobacillus stearothermophilus* bacterial spores and is intended for routine monitoring of the efficacy of steam sterilization processes and for monitoring processed loads, providing visual confirmation in 20 seconds. The IBI-05 is not recommended and should not be used for qualification testing purposes.

Gravity-displacement Steam Sterilization Cycles: 121 ºC for 30 minutes, 132 ºC for 25 minutes, 132 ºC for 15 minutes, 132 ºC for 10 minutes, 132 ºC for 3 minutes

Dynamic-air-removal Steam Sterilization Cycles: 132 ºC, 4 minutes 135 ºC, 3 minutes

Operational Principles:

Place an IBI-05 in the most difficult area to sterilize in a load. When the cycle is complete, the IBI-05 is removed, and the base is detached to gain access to the biological tablet. The Indicator Solution supplied with the IBI is applied dropwise onto the biological tablet to activate and obtain a visual result without incubation.

The activated IBI-05 must 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 True Indicating InstaTRU™ Instant Biological Indicator for Steam (IBI-05) (K251559)	Predicate Terragene Bionova Photon Biological Indicator (BT225) (DEN220042)	Comparison
Intended Use: Method of Sterilization	Gravity-displacement Steam Sterilization Cycles: 121 ºC for 30 minutes, 132 ºC for 25 minutes, 132 ºC for 15 minutes, 132 ºC for 10 minutes, 132 ºC for 3 minutes. Dynamic-air-removal Steam Sterilization Cycles: 132 ºC, 4 minutes 135 ºC, 3 minutes.	Gravity-displacement Steam Sterilization Cycles: 132 ºC for 25 minutes, 132 ºC for 15 minutes, 132 ºC for 10 minutes, 135 ºC for 10 minutes. Dynamic-air-removal Steam Sterilization Cycles: 132 ºC, 4 minutes 135 ºC, 3 minutes.	Similar
Product Code	QVB	QVB	Same
FDA Regulation	21 CFR§ 880.2806	21 CFR§ 880.2806	Same
Indications for Use (IFU)	The True Indicating Instant Biological Indicator for Steam (IBI-05) is a Biological Indicator inoculated with a minimum of 10^5 viable *Geobacillus stearothermophilus* bacterial spores and is intended for routine monitoring of the efficacy of steam sterilization processes, and for releasing processed loads, providing visual confirmation in 20 seconds. The IBI-05 is not recommended and should not be used for qualification testing purposes.	The 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 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.	Similar
Organism	*Geobacillus stearothermophilus* 7953	*Geobacillus stearothermophilus* 7953	Same

Feature	Subject Device True Indicating Instant Biological Indicator for Steam (K251559)	Predicate Terragene Bionova Photon Biological Indicator (BT225) (DEN220042)	Comparison
Mechanism of Action	Enzymes, produced by the organism, react with a coenzyme within the Indicator Solution media to produce a formazan complex moiety used to predict the outgrowth of the bacterial spore	Radial configuration of light source and detectors optimize the excitation of a fluorochrome and its subsequent detection from a fluorescence reading, to predict the outgrowth of the bacterial spore	Different The mechanism of action for the subject device is an enzymatic reaction with a qualitative result and the predicate is fluorescence detection with a quantitative result.
Viable Spore Population	$\geq 10^5$ or greater	$\geq 10^6$ or greater	Similar
Incubation Conditions	55 - 65 °C	60°C	Similar
Accessories	Indicator Solution is used to determine Instant sterilization results. Standard incubator is used to determine colorimetric results	Fluorescence Reader used to determine Instant sterilization results. Incubator used to determine colorimetric results.	Different The subject device does not require a reader.
Chemical Indicator	None	Process indicator that turns from pink to brown.	Different The subject device does not include a chemical indicator.
Reduced Incubation Time (RIT)	RIT at 55-65°C is determined within 10 hours for outgrowth of spores of the Optional SCBI.	Subject device does not require heated incubation for 7 second instant result. RIT at 60°C is determined within 48 hours for outgrowth of spores	Similar The subject device includes an optional SCBI.
Hold-Time	72 Hours	14 Days	Different
D-Value	D121 ≥ 1.5 min D132 ≥ 10 s D135 ≥ 8 s	D121 ≥ 1.5 min D132 ≥ 10 s D135 ≥ 8 s	Same
Z-Value	≥ 10°C	≥ 10°C	Same
Probable Limit of Detection	1 – 100 CFUs	1 – 100 CFUs	Different The subject device uses a different method to estimate probable LOD because it is a qualitative assay.
Sensitivity	Greater than 97%	Greater than 97%	Same
Specificity	Greater than 95%	Less than 95%	Different
End Point Color Stability for IBI & SCBI	7 Days	7 Days	Same
Shelf Life	20 months	18 Months	Similar

Summary of Nonclinical Testing – InstaTRU™ Instant Biological Indicator for Steam (IBI-05)

Testing was conducted 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
- United Sates Pharmacopeia, <55> Biological Indicators – Resistance Performance Tests
- Clinical and Laboratory Standards, Evaluation of Qualitative, Binary Output Examination Performance (EP12) 3rd Edition: Appendix C
- Clinical and Laboratory Standards, User Protocol for Evaluation of Qualitative Test Performance (EP12-A2) 2nd Edition

Summary of Nonclinical Testing Table

Name of Test	Purpose	Acceptance Criteria	Subject Device Result
Viable Spore Population for both the IBI and the SCBI	Determine the population of the IBI per the manufacturer's procedure following ISO 11138-1	≥1.0 x 10^5	**PASS** ≥1.0 x 10^5
D value for both the IBI and the SCBI	Determine the resistance of the IBI following ISO 11138-1 and 11138-3	D121 ≥ 1.5 min D132 ≥ 10 s D135 ≥ 8 s	**PASS** D121 ≥ 1.5 min D132 ≥ 18 s D135 ≥ 18 s
z value for both the IBI and the SCBI	Determine the z-value of the IBI per ISO 11138-1 and 11138-3	≥10	**PASS** ≥17.3°C
Survival Time	Determine the exposure time for all IBI'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** IBI: 121°C ≥ 6.8 min 132°C ≥ 1.4 min 135°C ≥ 1.3 min SCBI: 121°C ≥ 5.7 min 132°C ≥ 1.0 min 135°C ≥ 1.0 min
Kill Time	Determine the exposure time for all IBI'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** IBI: 121°C ≤ 16.3 min 132°C ≤ 3.3 min 135°C ≤ 3.3 min SCBI: 121°C ≤ 15.7 min 132°C ≤ 2.7 min 135°C ≤ 2.7 mi
Reduced Incubation Time	Determine the Reduced Incubation Time outlined in Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	10-hour results with the conventional incubation time of 7 days for the SCBI (Tablet is not incubated)	**PASS** RIT at 55-65 degrees C is determined within a minimum of 10 hours for outgrowth of spores for the SCBI.
Hold Time for both the IBI and the SCBI	Determine the length of time that an exposed IBI 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** Performance not affected if used within 72 hours of exposure to steam sterilization

Name of Test	Purpose	Acceptance Criteria	Subject Device Result
End Point Color Stability For the SCBI	Determine the End Point Color Stability for the Biological Tablet and the SCBI Media per Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Negative Result = purple media color for SCBI Media Positive Result = Yellow media color for SCBI Media	**PASS** Purple media color for SCBI Media remained for 7 days Yellow media color for SCBI Media remained for 7 days
End Point Color Stability For the Biological Tablet	Determine the End Point Color Stability for the Biological Tablet and the SCBI Media per Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Negative Result = White to Off-White color of Tablet Positive Result = Pink/Red color of Tablet	**PASS** White to Off-White color of Tablet remained for 7 days Pink/Red color of Tablet remained for 7 days
Probable Limit of Detection, Sensitivity, Specificity	Determine the probable LOD, Sensitivity and Specificity for the IBI	Probable LOD = 1 CFU Sensitivity > 95% Specificity > 95%	**PASS** Probable LOD = 1 CFU Sensitivity > 95% Specificity > 95%
Simulated Use	Determine the simulated use of the Instant IBI in a sterilizer per Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission	Demonstrates a survival (positive) result when exposed to abbreviated (sub lethal) cycle, and all kill (negative) in full and half cycles	**PASS** Abbreviated (sub lethal) cycles – growth Half cycles – no growth Full cycles – no growth

Conclusion: Based on the non-clinical performance data, the True Indicating InstaTRU™ Instant Biological Indicator for Steam (IBI-05) is as safe, as effective, and performs as well as or better than the legally marketed predicate, Terragene Bionova Photon Biological Indicator (BT225) (DEN220042) Class II (21 CFR 880.2806), under product code QVB.