January 17, 2025

True Indicating, LLC
Thomas Riha
Chief Scientific Officer
946 Kane St
Suite A
Toledo, Ohio 43612

Re: K242860
Trade/Device Name: Type 5 Integrating Indicator for Steam (CSPN-15)
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: September 20, 2024
Received: September 20, 2024

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 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.01.17 14:10:30 -05'00'

for: Christopher K. Dugard
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.

Submission Number *(if known)*

K242860

Device Name

Type 5 Integrating Indicator for Steam (CSPN-15)

Indications for Use *(Describe)*

The True Indicating Type 5 Integrating Indicator for Steam CSPN-15 is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Gravity Displacement: 121° C for 30 minutes, 132° C for 15 minutes, 132° C for 25 minutes, 132° C for 3 minutes, 135° C for 10 minutes;

Dynamic Air Removal (Vacuum Assist): 132° C for 4 minutes, 135° C for 3 minutes.

Minimum Stated Values as determined in a resistometer:
SV121°C/16.5 min., SV132°C/2.0min, SV134°C/1.4 min. SV135°C/1.2 min.

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.

K242860 - 510(k) Summary

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Prepared on: January 14, 2025

Device Name: Type 5 Integrating Indicator for Steam (CSPN-15)

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

Predicate Devices: (Legally Marketed) Terragene Integron® IT26-1YS (K191021)

Device Description: The True Indicating Chemical Indicator for Steam CSPN-15 consists of a white polyester substrate with acrylic adhesive married to a paper substrate. The paper substrate (with acrylic adhesive) has True Indicating water-based steam indicating ink, ISPN-01 (pink to dark brown/black), and general artwork printed. After printing, the top layer of the Type 5 Integrating Indicator strip is covered with a clear colorless polyester laminate with acrylic adhesive. The Integrating Indicators have been designed for Steam sterilization processes, ensuring the effectiveness of sterilization by monitoring all critical process variables (time, temperature and steam). The pink indicating ink was developed to turn to dark and conceal the word “NOT” when a theoretical spore population reaches its kill time, indicating integration condition has been reached. This condition is calibrated with the kill time of a 10^5 Geobacillus stearothermophilus spore population, calculated in BIER (Biological Indicator Evaluator Resistometer).

Indications for Use: The True Indicating Type 5 Integrating Indicator for Steam CSPN-15 is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Gravity Displacement: 121° C for 30 minutes, 132° C for 15 minutes, 132° C for 25 minutes, 132° C for 3 minutes, 135° C for 10 minutes;

Dynamic Air Removal (Vacuum Assist): 132° C for 4 minutes, 135° C for 3 minutes.

Minimum Stated Values as determined in a resistometer:
SV121°C/16.5 min., SV132°C/2.0min, SV134°C/1.4 min. SV135°C/1.2 min

Operational Principles:

The Type 5 Integrating Indicator for Steam CSPN-15 is intended for use with individual units, (e.g. packs, pouches, containers, trays, or containment devices) to demonstrate that the goods have been exposed to the critical parameters of a steam sterilization process.

The Type 5 Integrating Indicator for Steam CSPN-15 will transition from an initial color of pink (product code CSPN-15) to a dark brown/black signal color and conceal the word “NOT” when exposed to high temperature steam at various time and temperature intervals.

Technological Characteristic Comparison Table

Feature	Subject Device True Indicating Type 5 Integrating Indicator for Steam CSPN-15	Predicate Device Terragene Integron® IT26-1YS (K191021)	Comparison
Intended Use	Integrating indicator for steam sterilization	Integrating indicator for steam sterilization	Identical
Product Code	JOJ	JOJ	Identical
FDA Regulation	21 CFR§ 880.2800	21 CFR§ 880.2800	Identical
Indications for Use (IFU)	The True Indicating Type 5 Integrating Indicator for Steam CSPN-15 is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Gravity Displacement: 121° C for 30 minutes, 132° C for 15 minutes, 132° C for 25 minutes, 132° C for 3 minutes, 132° C for 10 minutes; Dynamic Air Removal (Vacuum Assist): 132° C for 4 minutes, 135° C for 3 minutes. Minimum Stated Values as determined in a resistometer: SV121°C/16.5 min., SV132°C/2.0min, SV134°C/1.4 min. SV135°C/1.2 min.	The integrator Terragene Integron® IT26-1YS is designed to chemically react over time with the critical parameters of steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Gravity Displacement: 121° C for 30 minutes, 132° C for 15 minutes, 132° C for 25 minutes, 135° C for 10 minutes; Dynamic Air Removal (Vacuum Assist): 132° C for 4 minutes, 135° C for 3 minutes. SV121° C/16.5 min. SV132° C/2.0 min, SV135° C/1.2 min.	Similar
Device Design	Paper Strip printed with pink chemical indicator ink with polyester overlaminate applied over the top of the indicating ink strip	Paper strip printed with yellow chemical indicator ink with poly overlaminate applied over the top of the indicating ink strip	Similar
Indicator Agent	Sulfide based chemical to yield color transition	Sulfide based chemical to yield color transition	Similar
Endpoint Specification	Dark brown/black color change	Dark brown/black color change	Identical
End Point Stability	6 Month	6 Months	Identical
Shelf Life	48 Months	60 Months	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 Chemical Indicator for Steam CSPN-15 over the range of the shelf life:

- Performance Exposure Studies were conducted per ISO 11140-1:2014 for a Type 5 Integrator for Steam, and Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff
- End Point Stability of the achieved signal color was evaluated for a period of months per Guidance for Industry and FDA Staff Chemical Indicator (CI) Premarket Notification [510(k)] Submissions.
- Offset-Transference testing was conducted per ISO 11140-1
- Simulated Use (Healthcare Steam Cycles) – Steam Exposure cycles were tested side-by-side with a biological indicator utilizing various loads per Guidance for Industry and FDA Staff Chemical Indicator (CI) Premarket Notification and True Indicating Protocols
- Shelf-life of product code CSPN-15 per Guidance for Industry and FDA Staff Chemical Indicator (CI) Premarket Notification and True Indicating Protocols

Summary of Nonclinical Testing – Type 5 Integrating Indicator for Steam CSPN-15

Testing was conducted on the Type 5 Integrating Indicator for Steam CSPN-15 following the FDA guidance and the standards below:

- Guidance for Industry and FDA Staff, Chemical Indicator (CI) Premarket Notification [510(k)] Submissions,
- ISO 11140-1:2014 Sterilization of health care products – Chemical indicators, Part 1: General requirements (Type 5 Integrator for Steam)

Summary of Nonclinical Testing Table

Name of Test	Purpose	Acceptance Criteria	Subject Device Result
Steam Resistometer Testing	To identify and test the pass/fail criteria for each critical parameter and provide the pass/fail results to show how the Type 5 Integrating Indicator reacts to 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 Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff. Integrator temperature coefficient and correlation coefficient are calculated to confirm alignment to biological indicator performance.	Pass result (end signal color achieved for all product codes) at the value for each temperature claimed: 121°C for 16.5 minutes 132°C for 2.0 minutes 134°C for 1.4 minutes 135°C for 1.2 minutes	**PASS**
		Fail result (end signal color not achieved) at the value for each temperature claimed: 120°C for 14.025 minutes 131°C for 1.7 minutes 133°C for 1.19 minutes 134°C for 1.02 minutes	
		Integrator temperature coefficient 10 – 27 °C	**PASS**
		Correlation coefficient $\geq$ 0.9	**PASS**
Hospital Steam Sterilizer Testing	Determine if the Type 5 Integrating indicator reach specified endpoint color of dark brown/black when combined with a sterilization load and exposed to the sterilization cycle for which it is intended according to Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff.	Pass result (signal color achieved for all product codes) at the value for each temperature claimed in combination of a sterilization load: Gravity Displacement: 121° C for 30 minutes, 132° C for 15 minutes, 132° C for 25 minutes, 132° C for 3 minutes, 135° C for 10 minutes; Dynamic Air Removal (Vacuum Assist): 132° C for 4 minutes, 135° C for 3 minutes.	**PASS**
Dry Heat Testing	Demonstrate that the Chemical Indicator for Steam does not change color following a dry heat cycle according to ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements and Premarket Notification [510(k)] Submissions for Chemical Indicators - Guidance for Industry and FDA Staff	Fail result when exposed to dry heat alone for 30 minutes (±1 minute) at 140°C (±2°C)	**PASS**

End Point Stability	Determine the length of time that an exposed Chemical Indicator for Steam retains its post-exposure signal color per Guidance for Industry and Staff – Chemical Indicator (CI) Premarket Notification [510(k)] Submission	6 Months	**PASS**
Side-by-Side Testing with a Biological Indicator	Confirm Integrators are parallel (or more robust) in performance to biological indicators (BI).	Chemical Integrator does not reach endpoint before BIs are inactivated	**PASS**
Offset/Transference	Demonstrate the chemical indicators do not bleed or offset to substrate which it's applied according to ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements.	The chemical indicators shall not offset or bleed, penetrate the substrate to which it is applied, or materials in which it is in contact before, during or after the sterilization cycles for which it is designed	**PASS**

Conclusion: The conclusions drawn from the nonclinical tests demonstrate that the subject device, the True Indicating Type 5 Integrating Indicator for Steam CSPN-15 is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Terragene Integron® IT26-1YS (K191021), Class II (21 CFR 880.2800), product code JOJ.