December 2, 2022

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

Re: K220778
Trade/Device Name: Chemical Indicator for Steam
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: May 12, 2022
Received: November 1, 2022

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,

Christopher K. Dugard -S

for 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)*
K220778

Device Name
Chemical Indicator for Steam

Indications for Use *(Describe)*
The Chemical Indicator for Steam is intended for use with individual materials (i.e. pouches, packs, trays) to demonstrate the material has been exposed to a steam sterilization process to distinguish between processed and unprocessed goods.

The Chemical Indicator for Steam can transition from an initial color of yellow and turn to a dark brown/black color for Product Code: CSYN-US, pink to a dark brown/black color for Product Code: CSPN-US, and blue to a dark brown/black color for Product Code: CSBN-US when exposed to high temperature steam at the following time and temperature intervals as process indicators:

Gravity: 121℃/250 F - 30 minutes (wrapped/porous)

Pre-vacuum: 132℃/270 F - 3 minutes (unwrapped/nonporous)
Pre-vacuum: 132℃/270 F - 4 minutes (wrapped/porous)
Pre-vacuum: 134℃/273 F - 4 minutes (wrapped/porous)
Pre-vacuum: 135℃/275 F - 3 minutes (wrapped/porous and unwrapped/nonporous, mixed load)

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.

K220778
510(k) Summary

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: Tom Riha
Chief Scientific Officer
P: 248 982 6492
F: 419 470 8899
E: tom.riha@trueindicating.com

Julie Wheeler
President
P:419 304 6535
F: 419 470 8899
julie.wheeler@trueindicating.com

Prepared on: November 28, 2022

Device Name: Chemical Indicator for Steam

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

Predicate Devices: (Legally Marketed) Lead-free Chemical Indicators for Steam Sterilization (K181788)

Description of Device: The True Indicating Lead-Free Chemical Indicator for Steam product codes CSYN-US (yellow to dark), CSPN-US (pink to dark), and CSBN-US (blue to dark), all turn a permanent dark brown/black color when exposed to high temperature steam.

Indications for Use: The Chemical Indicator for Steam is intended for use with individual materials (i.e. pouches, packs, trays) to demonstrate the material has been exposed to a steam sterilization process to distinguish between processed and unprocessed goods.

The Chemical Indicator for Steam can transition from an initial color of yellow and turn to a dark brown/black color for Product Code: CSYN-US, pink to a dark brown/black color for Product Code: CSPN-US, and blue to a dark brown/black color for Product Code: CSBN-US when exposed to high temperature steam at the following time and temperature intervals as process indicators:

Gravity:	121°C/250 F - 30 minutes (wrapped/porous)
Pre-vacuum:	132°C/270 F - 3 minutes (unwrapped/nonporous)
Pre-vacuum:	132°C/270 F - 4 minutes (wrapped/porous)
Pre-vacuum:	134°C/273 F - 4 minutes (wrapped/porous)
Pre-vacuum:	135°C/275 F - 3 minutes (wrapped/porous and unwrapped/nonporous, mixed load)

Operational Principles: The Chemical Indicator for Steam is intended for use with individual units, (e.g. packs, containers) to demonstrate that the goods have been exposed to a steam sterilization process and to distinguish between processed and unprocessed goods.

Technological Characteristic Comparison Table

Feature	Subject Device (K220778)	Predicate Device (K181788)	Comparison
Intended Use	Process indicator for steam sterilization	Process indicator for steam sterilization	Same
Product Code	JOJ	JOJ	Same
Regulation	21 CFR§ 880.2800	21 CFR§ 880.2800	Same
Indications for Use (IFU)	The Chemical Indicator for Steam is intended for use with individual materials (i.e. pouches, packs, trays) to demonstrate the material has been exposed to a steam sterilization process to distinguish between processed and unprocessed goods. The Chemical Indicator for Steam can transition from an initial color of yellow and turn to a dark brown/black color for Product Code: CSYN-US, pink to a dark brown/black color for Product Code: CSPN-US, and blue to a dark brown/black color for Product Code: CSBN-US when exposed to high temperature steam at the following time and temperature intervals as process indicators: Gravity: 121°C/250 F - 30 minutes (wrapped/porous) Pre-vacuum: 132°C/270 F - 3 minutes (unwrapped/nonporous) Prevacuum: 132°C/270 F - 4 minutes (wrapped/porous) Prevacuum: 134°C/273 F - 4 minutes (wrapped/porous) Prevacuum: 135°C/275 F - 3 minutes (wrapped/porous and unwrapped/nonporous, mixed load)	The Kem Medical Lead-free Chemical Indicators for Steam Sterilization are designed for use by a health care provider to demonstrate that the unit or load has been exposed to a steam sterilization process, and to distinguish between processed and unprocessed units or loads. Use the Kem Medical Lead-free Chemical Indicators for Steam Sterilization in the validated steam sterilization processes described below: Gravity: 121°C/250 F - 30 minutes (wrapped/porous) Gravity: 132°C/270 F - 3 minutes (unwrapped/nonporous) Gravity: 132°C/270 F - 15 minutes (wrapped/porous) Gravity: 135°C/275 F - 3 minutes (unwrapped/nonporous) Gravity: 135°C/275 F - 10 minutes (wrapped/porous or unwrapped/nonporous, mixed load) Vacuum assisted (prevacuum): 132°C/270 F - 3 minutes (unwrapped/nonporous) Vacuum assisted (prevacuum): 132°C/270 F - 4 minutes (wrapped/porous) Vacuum assisted (prevacuum): 134°C/273 F - 4 minutes (wrapped/porous) Vacuum assisted (prevacuum): 135°C/275 F - 3 minutes (wrapped/porous or unwrapped/nonporous, mixed load)	Similar
Device Design	Paper Strip printed with Bismuth based chemical indicator ink with polyester overlaminate applied over the entire indicating ink strip	Paper dot/strip/card printed with bismuth sulfide based chemical indicator ink	Similar

Feature	Subject Device (K220778)	Predicate Device (K181788)	Comparison
Indicator Agent	Bismuth based chemical to yield color transition	Bismuth based chemical to yield color transition	Same
Endpoint Specification	Dark brown/black color change	Dark brown/black color change	Same
End Point Stability	1 Month	6 Months	Similar
Shelf Life	30 Months	12 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 over the range of the shelf life:

- Performance Exposure Studies were conducted per ISO 11140-1
- End Point Stability of the achieved signal color was evaluated for a period of days 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 utilizing various loads per Guidance for Industry and FDA Staff Chemical Indicator (CI) Premarket Notification and True Indicating Protocols

Summary of Nonclinical Testing – Chemical Indicator for Steam

Testing was conducted on the Chemical Indicator for Steam 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

Summary of Nonclinical Testing Table

Name of Test	Purpose	Acceptance Criteria	Subject Device Result
Steam Resistometer Testing	To test the pass/fail criteria for each critical cycle parameter and provide the pass/fail results to show how the chemical 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.	Pass result (signal color achieved for all product codes) at the value for each temperature claimed: 121°C for 10 minutes 134°C for 2 minutes 135°C for 2 minutes	**PASS**
		Fail result (signal color not achieved for all product codes) at the value for each temperature claimed: 121°C for 2 minutes 134°C for 0.3 minutes 135°C for 0.3 minutes	
Hospital Steam Sterilizer Testing	Determine if the chemical indicators 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: 121°C/250 F - 30 minutes (wrapped/porous) • Vacuum assisted (prevacuum): 132°C/270 F - 3 minutes (unwrapped/nonporous) • Vacuum assisted (prevacuum): 132°C/270 F - 4 minutes (wrapped/porous) • Vacuum assisted (prevacuum): 134°C/273 F - 4 minutes (wrapped/porous) • Vacuum assisted (prevacuum): 135°C/275 F - 3 minutes (wrapped/porous and unwrapped/nonporous, mixed load)	**PASS**

Name of Test	Purpose	Acceptance Criteria	Subject Device Result
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	1 Month	**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 conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K220778, the Chemical Indicator for Steam, is as safe, as effective, and performs as well or better than the legally marketed predicate device cleared under K181788.