August 2, 2019

Intertape Polymer Inc.
% Gary Socola
President
Highpower Validation Testing & Lab Service's Inc.
125 Highpower Road
Rochester, New York 14623

Re: K191741
Trade/Device Name: Intertape Polymer Inc., Type 1 Bismuth Process Indicator Steam Sterilization Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: June 28, 2019
Received: July 1, 2019

Dear Gary Socola:

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,

For Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K191741

Device Name
Intertape Polymer Inc., Type 1 Bismuth Process Indicator Steam Sterilization Tape

Indications for Use *(Describe)*
The Bismuth Process Indicator Steam Sterilization Tape is indicated for use in holding sterilization packs together and can be used in gravity sterilizers operating at 121°C for 30 minutes; 132 °C for 3 minutes; 132 °C for 10 minutes; 132 °C for 15 minutes; 135 °C for 3 minutes and 135 °C for 10 minutes or pre-vacuum sterilizers operating at 132°C for 3 minutes; 132 °C for 4 minutes; 134 °C for 3 minutes; 134 °C for 4 minutes and 135°C for 3 minutes. The indicator lines turn dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items.

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

**SUBMITTER INFORMATION:** (K191741 Page 1 of 3)


| | |
|---|---|
| Address: | Intertape Polymer Group<br>100 Paramount Dr Suite 300<br>Sarasota, FL, US 34232 |
| Phone: | 618-303-2423 |
| Fax: | 514-745-0764 |
| Contact Person: | Michael Bryant<br>US Agent |
| Date of Summary: | July 31st, 2019 |


**DEVICE INFORMATION:**

| | |
|---|---|
| Device Trade Name: | Intertape Polymer Inc.,<br>Type 1 Bismuth Process Indicator Steam Sterilization Tape |
| Common Name: | Process Indicator |
| Device Classification: | Indicator, Physical/Chemical Sterilization Process |
| Device Class: | Class II, 21 CFR § 880.2800(b) |
| Product Code: | JOJ |

**PREDICATE DEVICE:**

Cantech, Intertape Polymer Inc., Ltd. Process Indicator Tape for Steam Sterilization (K140940 and K161024) (Formerly Canadian Technical Tape)

**DEVICE DESCRIPTION (MODEL 146 & MODEL 147):**

The process indicator tape distinguishes between items processed and unprocessed in both gravity discharge and pre-vacuum steam sterilization cycles. The tape is made of a saturated crepe paper printed with beige indicator lines that turn to dark brown/black when proper levels of moisture and temperature have been achieved. The tape adheres on contact and stays in place through live steam pressure.

**INTENDED USE:**

A physical/chemical sterilization process indicator is a single use device intended to be used by a health care provider to distinguish between sterilization processed and unprocessed units.

**INDICATIONS FOR USE (IFU):**

The Bismuth Process Indicator Steam Sterilization Tape is indicated for use in holding sterilization packs together and can be used in gravity sterilizers operating at 121°C for 30 minutes; 132 °C for 3 minutes; 132 °C for 10 minutes; 132 °C for 15 minutes; 135 °C for 3 minutes and 135 °C for 10 minutes or pre-vacuum sterilizers operating at 132°C for 3 minutes; 132 °C for 4 minutes; 134 °C for 3 minutes; 134 °C for 4 minutes and 135°C for 3 minutes. The indicator lines turn dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items.

# 510(K) SUMMARY

**PERFORMANCE STANDARD TESTING:** (K191741 Page 2 of 3)

Testing was performed in accordance with ANSI/AAMI/ISO 11140-1:2014 - Sterilization of health care products - Chemical indicators - Part 1: General requirements and the Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Chemical Indicators.

**TECHNOLOGICAL CHARACTERISTICS:**

Shown below is the comparison of the proposed device with the predicate device and reference device.

**COMPARISON OF THE PROPOSED DEVICE TO THE PREDICATE**

| ELEMENT | SUBJECT DEVICE (K191741) | CANTECH PREDICATE DEVICE (K140940) | CANTECH REFERENCE DEVICE (K161024) |
|---|---|---|---|
| **Intended Use** | Process Indicator Tape | Process Indicator Tape | Process Indicator Tape |
| **Device Design** | Crepe paper printed with indicator lines. Provided in natural and blue in widths of approximately 0.5", 0.75" and 1" (12mm, 18mm and 24mm). | Crepe paper printed with indicator lines. Provided in natural and blue in widths of approximately 0.5", 0.75" and 1" (12mm, 18mm and 24mm). | Crepe paper printed with indicator lines. Provided in natural and blue in widths of approximately 0.5", 0.75" and 1" (12mm, 18mm and 24mm). |
| **Indicator Agent** | Steam Indicator Ink (made from Bismuth) | Steam Indicator Ink (made from Lead) | Steam Indicator Ink (made from Copper) |
| **Sterilization Method (Steam)** | Gravity<br>121$^0$C @ 30min<br>132$^0$C @ 3min<br>132$^0$C @ 10min<br>132$^0$C @ 15min<br>135$^0$C @ 3min<br>135$^0$C @ 10min<br>Pre-vacuum<br>132$^0$C @ 3min<br>132$^0$C @ 4min<br>134$^0$C @ 3min<br>134$^0$C @ 4min<br>135$^0$C @ 3min | Gravity<br>121°C @ 30 minutes<br>135°C @ 3 minutes<br>Pre-vacuum<br>132°C @ 4 minutes | Gravity<br>121°C @ 30 minutes<br>135°C @ 3 minutes<br>Pre-vacuum<br>132°C @ 4 minutes |
| **Endpoint Specifications** | 121° C for 10 minutes<br>132-135° C for 2 minutes. | 121° C for 10 minutes<br>132-135° C for 2 minutes. | 121° C for 10 minutes<br>132-135° C for 2 minutes. |
| **Shelf-life** | 2 years | 3 years | 3 years |
| **Indications for Use** | The Bismuth Process Indicator Steam Sterilization Tape is indicated for use in holding sterilization packs together and can be used in gravity sterilizers operating at 121°C for 30 minutes; 132 °C for 3 minutes; 132 °C for 10 minutes; 132 °C for 15 minutes; 135 °C for 3 minutes and 135 °C for 10 minutes or pre-vacuum sterilizers operating at 132°C for 3 minutes; 132 °C for 4 minutes; 134 °C for 3 minutes; 134 °C for 4 minutes and 135°C for 3 minutes. The indicator lines turn dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items. | The Process Indicator Tape for Steam Sterilization is indicated for use in holding sterilization packs together and can be used in gravity sterilizers operating at 121°C for 30 minutes or pre-vacuum sterilizers operating at 132°C for 4 minutes and 135°C for 3 minutes. The indicator stripes turn dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items. | The Canadian Technical Tape, Ltd. LF Process Indicator Steam Sterilization Tape is indicated for use in holding sterilization packs together and can be used in gravity sterilizers operating at 121°C for 30 minutes or pre-vacuum sterilizers operating at 132°C for 4 minutes and 135°C for 3 minutes. The indicator stripes turn dark brown/black when exposed to steam sterilization conditions, thus providing an indication of processed items. |
| **Performance Standards** | ANSI/AAMI/ISO 11140-1:2014 | ANSI/AAMI/ISO 11140-1:2005 | ANSI/AAMI/ISO 11140-1:2014 |

**Comparison conclusion:** The subject device has the same Indications for Use, intended use, technical characteristics and functional characteristics as the predicate device and reference device.

# 510(K) SUMMARY

**SUMMARY OF NONCLINICAL TESTING:** (K191741 Page 3 of 3)

The non-clinical testing that has been performed has been found to meet all predetermined acceptance criteria.

| Test | Description | Acceptance Criteria | Results |
|---|---|---|---|
| Performance Testing for a Type 1 Steam Process Indicator - ANSI/AAMI/ISO 11140-1 | Pass and fail testing in a steam resistometer according to Table 2 of ISO 11140-1:2014 | Pass - Visual Change as specified by manufacturer.<br>Fail - No change or a change that is markedly different from change specified by the manufacturer | Passed |
| Resistometer Performance Testing for a Type 1 Steam Process Indicator - FDA Chemical Indicator Guidance Document | Pass and fail testing in a steam resistometer according to the requirements in Table 3 of the FDA guidance document on Chemical Indicators | Pass - Visual Change as specified by manufacturer.<br>Fail - No change or a change that is markedly different from change specified by the manufacturer | Passed |
| In Use Testing in FDA 510k Cleared Steam Sterilizers - FDA Chemical Indicator Guidance Document | Pass and fail testing in cleared healthcare steam sterilizers according to the requirements in section VII "Performance Characteristics" of the FDA guidance document on Chemical Indicators | Pass - Visual Change as specified by manufacturer.<br>Fail - No change or a change that is markedly different from change specified by the manufacturer | Passed |
| Biocompatibility/Leach Off Testing - FDA Chemical Indicator Guidance Document | Cytotoxicity Testing to the requirements in section VIII "Biocompatibility" of the FDA guidance document on Chemical Indicators and Leach Off test in accordance with ISO 11140-1, section 6.4.2. | Biocompatibility - None of the cultures treated with the test article show greater than a Mild reactivity (Grade 2).<br>Leach Off - The indicator agent shall not offset or bleed to the substrate to which it is applied, or materials in which it is in contact. | Passed |
| Endpoint Stability - ANSI/AAMI/ISO 11140-1 and FDA Chemical Indicator Guidance Document | End Point Stability was tested in accordance with ISO 11140-1, section 6.1.2. | Post processing, the endpoint color change shall remain unchanged for a period of not less than six months from the date of use, when stored under the conditions specified by the manufacturer. | Passed |
| Shelf Life - ANSI/AAMI/ISO 11140-1 and FDA Chemical Indicator Guidance Document | Pass and fail testing in a steam resistometer according to Table 2 of ISO 11140-1:2014 was performed in order to satisfy section X "Shelf Life" of the FDA guidance document on Chemical Indicators | Pass - Visual Change as specified by manufacturer.<br>Fail - No change or a change that is markedly different from change specified by the manufacturer | Passed |
| Pressure Sensitive Tape Council (PSTC) International Standards Test for Tape Adhesion - PSTC-101 and PSTC-131 Sterilization Tape Standards | Internal tape adhesion test performed in accordance with the PSTC-101 and PSTC-131 International Tape Standards | The average force and displacement values (in Newtons) of five tests shall meet the manufacturers' internal specification. | Passed |
| Post Processing Visual Adhesive Test for Wrapped Packages | Test performed in response to a request from the FDA in the predicate K140940 clearance | All test samples shall demonstrate proper adhesion by not lifting from sterilization wrap after steam sterilization and proper drying time. | Passed |

**CONCLUSION:**

Based on the conclusions drawn from the nonclinical tests demonstrates that the Intertape Polymer Inc., Type 1 Bismuth Process Indicator Steam Sterilization Tape is as safe, as effective, and performs as well as or better than the legally marketed predicate device.