February 20, 2026

Intertape Polymer Group
℅ Mike Nolan
Owner
FLX Consulting
3192 Wheeler Station Rd.
Bloomfield, New York 14469

Re: K260181
Trade/Device Name: LF Process Indicator Tape for Steam Sterilization
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: January 21, 2026
Received: January 21, 2026

Dear Mike Nolan:

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: 2026.02.20 13:53:19 -05'00'

Stephen Anisko
Acting 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.

510(k) Number *(if known)*
K260181

Device Name
LF Process Indicator Tape for Steam Sterilization

Indications for Use *(Describe)*
The LF Process Indicator Tape for Steam Sterilization is designed to use on disposable wraps for sealing packs that are exposed to steam sterilization. The tape distinguishes between items processed and unprocessed in both gravity discharge and pre-vacuum steam sterilization processes. It is intended for use 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. 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 green indicator lines turn dark brown/black once exposed to the steam process.

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.

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510(K) SUMMARY- K260181

SUBMITTER INFORMATION:

Intertape Polymer Group
100 Paramount Drive,
Suite 300
Sarasota FL, 34232

Phone: (941) 739-7630

Contact Person: Michael Johnson
VP Operational Excellence • Plant Overhead

Date of Summary: February 17, 2026

DEVICE INFORMATION:

Device Trade Name:	LF Process Indicator Tape for Steam Sterilization
Common Name:	Lead Free Process Indicator Tape
Device Classification:	Indicator, Physical/Chemical Sterilization Process
Device Class:	Class II, 21 CFR § 880.2800(b)
Product Code:	JOJ

PREDICATE DEVICE:

Intertape Polymer Group Process Indicator Tape for Steam Sterilization (K161024)

DEVICE DESCRIPTION:

The LF Process Indicator Tape for Steam Sterilization is designed to seal packs that are exposed to steam sterilization. The tape distinguishes between processed items and unprocessed in both gravity discharge and pre vacuum steam sterilization processes. Made of a saturated crepe paper printed with non-lead-based ink, the green indicator lines turn dark brown/black once exposed to the steam process. It is coated with a synthetic, solvent-free adhesive. This product is not made with natural rubber latex. Lead is not used in the manufacturing of the ink of indicator lines.

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 LF Process Indicator Tape for Steam Sterilization is designed to use on disposable wraps for sealing packs that are exposed to steam sterilization. The tape distinguishes between items processed and unprocessed in both gravity discharge and pre-vacuum steam sterilization processes. It is intended for use 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. 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 green indicator lines turn dark brown/black once exposed to the steam process.

PERFORMANCE STANDARD TESTING:

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.

DISCUSSION:

The subject device has the same, intended use, technical characteristics, as the predicate device and changes are made only to labeling to reflect extended IFU. Both provide a visual indication that packages have been exposed to the steam sterilization process. Both are made with the exact same materials and manufacturing process. The non-clinical testing that has been performed has been found to meet all predetermined acceptance criteria.

TECHNICAL CHARACTERISTICS COMPARISON OF THE SUBJECT DEVICE TO THE PREDICATE

ELEMENT	SUBJECT DEVICE (K260181)	PREDICATE (K161024)	COMPARISON
Intended Use	Process Indicator Tape	Process Indicator Tape	Same
Device Design	Crepe paper printed with indicator lines. Provided in natural and blue in widths of approximately 0.75" and 1" (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).	Similar
Indicator Agent	Steam Indicator Ink (not made from lead)	Steam Indicator Ink (not made from lead)	Same
Sterilization Method (Steam)	Gravity 121°C / 250°F; 30 minutes 132°C / 270°F; 3 minutes 132°C / 270°F; 10 minutes 132°C / 270°F; 15 minutes 135°C / 275°F; 3 minutes 135°C / 275°F; 10 minutes Dynamic air removal/pre-vacuum P/V 132°C / 270°F; 3 minutes 132°C / 270°F; 4 minutes 134°C / 273°F; 3 minutes 134°C / 273°F; 4 minutes	Gravity 121°C 30 minutes Pre-vacuum 132°C 4 minutes Gravity 135°C 3 minutes	Different - labeling has been updated to include additional validated steam sterilization cycles.
Endpoint Specifications	121°C for 10 minutes 132-135°C for 2 minutes	121°C for 10 minutes 132-135°C for 2 minutes	Same
Shelf-Life	3 years	3 years	Same

Indications for Use	The LF Process Indicator Tape for Steam Sterilization is designed to use on disposable wraps for sealing packs that are exposed to steam sterilization. The tape distinguishes between items processed and unprocessed in both gravity discharge and pre-vacuum steam sterilization processes. It is intended for use 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. 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 green indicator lines turn dark brown/black once exposed to the steam process.	The LF 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.	Different - labeling has been updated to include additional validated steam sterilization cycles.
Performance Standards	ANSI/AAMI/ISO 11140-1:2014	ANSI/AAMI/ISO 11140-1:2014	Same

SUMMARY OF NONCLINICAL TESTING:

The non-clinical testing that has been performed on multiple lots of indicators and each was found to meet all predetermined acceptance criteria.

Test	Description	Results
Performance Testing for a Class 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	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	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.	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.	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 to satisfy section X "Shelf Life" of the FDA guidance document on Chemical Indicators	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	Passed
Post Processing Visual Adhesive Test for Wrapped Packages	Test performed in healthcare steam sterilizers to demonstrate proper tape adhesion.	Passed

CONCLUSION:

The LF Process Indicator Tape for Steam Sterilization is as safe, as effective and performs as well as or better than the legally marketed predicate device, cleared under K161024.