DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 28, 2016

Canadian Technical Tape, Ltd.
% Gary Socola
President
Highpower Validation and Testing Lab Services Inc.
125 Highpower Rd.
Rochester, New York 14623

Re: K161024
Trade/Device Name: Canadian Technical Tape, Ltd. LF Process Indicator Steam Sterilization Tape
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: May 31, 2016
Received: June 1, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
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)*
K161024

Device Name

Canadian Technical Tape, Ltd. LF Process Indicator Steam Sterilization Tape

Indications for Use *(Describe)*

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.

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.

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510(K) SUMMARY

SUBMITTER INFORMATION:

Canadian Technical Tape, Ltd.
455 Côte-Vertu Blvd.
Montreal, Qubec, Canada
H4N 1E8

Phone:	(800) 334-1567
Fax:	(800) 334-1029
Contact Person:	Howard Cohen President
Date of Summary:	June 28th, 2016

DEVICE INFORMATION:

Device Trade Name:	Canadian Technical Tape, Ltd. LF Process Indicator Steam Sterilization Tape
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:

Canadian Technical Tape, Ltd. Process Indicator Tape for Steam Sterilization (K140940)

REFERENCE 510K DEVICE:

SteriTec Green Tape (K122555)

DEVICE DESCRIPTION (MODEL 143 & MODEL 144):

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 green 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 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 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.

SUBSTANTIAL EQUIVALENCE DISCUSSION:

The subject device has the same Indications for Use, intended use, technical characteristics and functional characteristics as the predicate device K140940. They provide a visual indication that packages have been exposed to the steam sterilization process. Each are made with the exact same manufacturing process.

COMPARISON OF THE PROPOSED DEVICE TO THE PREDICATE

ELEMENT	SUBJECT DEVICE	CANADIAN TAPE PREDICATE (K140940)	STERITEC REFERENCE (K122555)
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 in widths of approximately 0.5", 0.75" and 1" (12mm, 18mm and 24mm).
Indicator Agent	Steam Indicator Ink (not made from lead)	Steam Indicator Ink (made from lead)	Steam Indicator Ink (not made from lead)
Sterilization Method (Steam)	Gravity 121°C 30 minutes Pre-vacuum 132°C 4 minutes Gravity 135°C 3 minutes	Gravity 121°C 30 minutes Pre-vacuum 132°C 4 minutes Gravity 135°C 3 minutes	Gravity 121°C 30 minutes Pre-vacuum 132°C 4 minutes Gravity 135°C 3 minutes
Endpoint Specifications	121° C for 10 minutes 132-135° C for 2 minutes.	121° C for 10 minutes 132-135° C for 2 minutes.	121° C for 10 minutes 132-135° C for 2 minutes.
Shelf-life	3 years	3 years	3 years
Indications for Use	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.	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.	SteriTec Green Tape can be used in 121°C gravity sterilizers for 30 minutes or pre-vacuum sterilizers operating at 132°C for 4 minutes and 135°C for 3 minutes. Stripes turn black after exposure to steam sterilization conditions, thus providing identification of processed items.
Performance Standards	ANSI/AAMI/ISO 11140-1:2014	ANSI/AAMI/ISO 11140-1:2005(R) 2010	ANSI/AAMI/ISO 11140-1:2005(R) 2010

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
Resistometer Performance Testing for a Class 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	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 in order 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 response to a request from the FDA in the predicate K140940 clearance	Passed

CONCLUSION:

The Canadian Technical Tape, Ltd. LF Process Indicator Steam Sterilization Tape is substantially equivalent to the predicate device, as the devices are identical, share a common manufacturer, and share common intended use. The tape meets the performance claims for a type 1 process indicator according to ANSI/AAMI/ISO 11140-1:2014.