DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 27, 2014

Canadian Technical Tape, LTD
C/O Mr. Gary Socola
Official Correspondent
President
Highpower Validation Testing and Lab Services
125 Highpower Road
Rochester, NY 14623

Re: K140940
Trade/Device Name: Process Indicator Tape for Steam Sterilization
Regulation Number: 21 CFR 880.2800
Regulation Name: Physical/Chemical Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: September 19, 2014
Received: September 23, 2014

Dear Mr. 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" (21CFR 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,

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)*
K140940

Device Name

Process Indicator Tape for Steam Sterilization

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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3.0 510K SUMMARY

Submission Date: April 8, 2014

Summary Date: October 15th, 2014

Submitter Information:

Company Name: Canadian Technical Tape, Ltd.

Company Address: Canadian Technical Tape, Ltd.
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Montreal, QC, Canada H4N 1E8

Contact Person: Howard Cohen
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Device Information:

Trade Name: Process Indicator Tape for Steam Sterilization

Common Name: Process Indicator Tape

Classification Name: Physical/Chemical Sterilization Process Indicator

Product Code: JOJ

Device Class: Class II, *21 CFR 880.2800(b)*

Predicate Devices: Sterilization Process Indicator Tapes Model CI122 & CI123 (K001649) SteriTec Products, Incorporated

Device Description:

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 white 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.

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Indications for Use:

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.

Performance Standard Testing:

Testing was performed in accordance with ANSI/AAMI/ISO 11140-1:2005(R) 2010 - 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.

Comparison of the Proposed Device to the Predicate Device:

Characteristic	Predicate Device:	Proposed Device:
Intended Use	Process indicator tape for steam sterilization	Process indicator tape for steam sterilization
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).
Indicator Agent	Sulfur, lead carbonate hydroxide and magnesium oxide	Sulfur, lead carbonate hydroxide and magnesium oxide
Sterilization Method	The tape is intended for use as a steam sterilization cycle process indicator in gravity discharge and pre-vacuum steam sterilizers.	The tape is intended for use as a steam sterilization cycle process indicator in gravity discharge and pre-vacuum steam sterilizers.
Endpoint Specifications	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
Indications for use	SteriTec Autoclave and Blue Autoclave Tapes are for use holding sterilization packs together and as process indicators in gravity steam sterilizers operating at 121° C and pre-vacuum steam sterilizers operating at 132-134° C. The white indicator stripes on the tape turn black when exposed to steam sterilization providing 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.
Performance Standards	ANSI/AAMI ST-60	ISO 11140-1:2005, ANSI/AAMI/ISO 11140-1:2005(R)2010

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The proposed device is an identical product to the predicate device and both are manufactured by Canadian Technical Tape, Ltd.

Summary of Nonclinical Testing:

Test	Results
ANSI/AAMI/ISO 11140-1 - Performance Testing for a Class 1 Steam Process Indicator	Passed
FDA Chemical Indicator Guidance Document - Resistometer Performance Testing for a Class 1 Steam Process Indicator	Passed
In Use Testing - Steam Gravity and Pre-Vacuum 510 K Cleared Sterilizers	Passed
Biocompatibility/Leach Off Testing	Passed
Endpoint Stability	Passed
Shelf Life	Passed
PSTC-101 and PSTC-131 - Pressure Sensitive Tape Council (PSTC) International Standards Test for Tape Adhesion	Passed
Post Processing Visual Adhesive Test for Wrapped Packages	Passed

Conclusion:

The Process Indicator Tape for Steam Sterilization is substantially equivalent to the predicate device. The tape meets the performance claims for a class 1 process indicator according to ANSI/AAMI/ISO 11140-1:2005 (R) 2010 and raises no issues related to safety or effectiveness.