July 15, 2021

Crosstex International, Inc. (A Cantel Medical Company)
Pablo Martinez
Sr. Manager, Regulatory Affairs
10 Ranick Road
Hauppauge, New York 11788

Re: K200096
Trade/Device Name: Crosstex VH_2O_2 Chemical Indicators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: June 21, 2021
Received: June 24, 2021

Dear Pablo Martinez:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200096

Device Name
Crosstex International VH2O2 Chemical Indicators

Indications for Use *(Describe)*
A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Duo, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO® 1, V-PRO® 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH2O2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.

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."

Crosstex International, Inc.
6789 West Henrietta Road
Rush, NY 14543
Tel: (800) 722-1529

510(k) Summary for K200096
Crosstex VH_2O_2 Chemical Indicators

Manufacturer: Crosstex International, Inc.

Address: 6789 West Henrietta Road
Rush, NY 14543
(800) 722-1529

Official Contact: Pablo Martinez
Sr. Manager, Regulatory Affairs

Address: Crosstex International, Inc.
10 Ranick Road
Hauppauge, NY 11788
PabloM@Crosstex.com
(631) 257-1046

Date: July 14, 2021

1. Device Name and Classification:

Trade Name:	Crosstex VH_2O_2 Chemical Indicators
Common Name:	Chemical Indicator
Regulation No:	21CFR 880.2800 (b)
Classification Name:	Indicator, physical/chemical sterilization indicator
Product Code:	JOJ
Device Class:	II

2. Predicate Device:

510(K) Number:	K140566
Trade Name:	Crosstex/SPSmedical VH_2O_2 Chemical Indicators
Submitter/holder:	Crosstex International Inc. 6789 West Henrietta Road Rush, NY 14543 U.S.A.

3. Device Description

The Crosstex VH_2O_2 Chemical Indicators are intended for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX (Standard, Duo, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX, and Sterilucent™ PSD-85 sterilization processes. The Crosstex VH_2O_2 Chemical Indicators are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Chemical indicators change to a color of blue after exposure to vaporized hydrogen peroxide. Colors other than blue such as yellow/green should be treated as a process failure.

Crosstex International, Inc.
6789 West Henrietta Road
Rush, NY 14543
Tel: (800) 722-1529

4. Intended Use

The Crosstex VH_2O_2 Chemical Indicators are intended for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX (Standard, Duo, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX, and Sterilucent™ PSD-85 sterilization processes. The Crosstex VH_2O_2 Chemical Indicators are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Chemical indicators change to a color of blue after exposure to vaporized hydrogen peroxide. Colors other than blue such as yellow/green should be treated as a process failure.

5. Technological Characteristics Comparison

Table 1 - Technological Characteristics Comparison

Element	Proposed Device (K200096)	Predicate Device (K140566)	Comparison
Intended Use	The Crosstex VH_2O_2 Chemical Indicators are intended for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX (Standard, Duo, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX, and Sterilucent™ PSD-85 sterilization processes. The Crosstex VH_2O_2 Chemical Indicators are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Chemical indicators change to a color of blue after exposure to vaporized hydrogen peroxide. Colors other than blue such as yellow/green should be treated as a process failure.	The SPSmedical VH_2O_2 Indicators are intended for use as process indicators for all vaporized hydrogen peroxide cycles in the STERRAD® 100S, 200, 100NX, NX, STERIS® V-Pro 1, V-Pro 1 Plus, V-Pro maX and Sterilucent PSD-85 sterilization processes. They are intended to be used by health care providers with articles such as sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed items. Indicators change to a signal color of Blue after exposure to vapor hydrogen peroxide.	Similar
Indications for Use	A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Duo, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO® 1, V-PRO® 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.	A chemical indicator for monitoring all cycles within the STERRAD® 100S (Standard & Long), 200, 100NX (Standard, Flex & Express), NX (Standard & Advanced), STERIS® V-PRO™ 1, V-PRO™ 1 Plus (Lumen & Non-lumen), V-PRO® maX (Flexible, Lumen & Non-lumen) and Sterilucent™ PSD-85 (Lumen & Non-lumen). The VH_2O_2 Indicators are intended to be used by health care providers with sterilization wraps, containers, cassettes, or pouches to distinguish between processed and unprocessed units. Colors other than blue such as yellow/green should be treated as a process failure.	Similar
Device Design	Label, Card, Strip, Tape	Strip, Label, Tape, Card	Same
Endpoint Color	Signal Color of Blue	Signal Color of Blue	Same

Crosstex International, Inc.
6789 West Henrietta Road
Rush, NY 14543
Tel: (800) 722-1529

Table 1 - Technological Characteristics Comparison - *continued*

Element	Proposed Device (K200096)	Predicate Device (K140566)	Comparison
Indicator Agent	H_2O_2 Indicator Ink	H_2O_2 Indicator Ink	Same
Sterilization Method	Vaporized Hydrogen Peroxide	Vaporized Hydrogen Peroxide	Same
Device Materials	Synthetic Substrate	Synthetic Substrate	Same
Performance under ISO 11140-1 Complete reaction cycle	Passed	Passed	
Biocompatibility	Complies	Complies	Same
Performance under ISO 11140-1 Incomplete reaction cycle	Passed	Passed	Same
Shelf-life	Up to 2 years	Up to 2 years	Same
Non-Clinical Performance - STERRAD® 100NX® DUO Cycle sterilization cycle	Complete cycle turns blue with yellow/green intermediate.	Complete cycle turns blue with yellow/green intermediate.	Same

6. Summary of Non-Clinical Testing

Nonclinical testing and biocompatibility testing was performed to demonstrate that the subject device conforms to the standards and testing mentioned below:

Test Methodology	Purpose	Acceptance Criteria	Results
ANSI/AAMI/ISO 11140-1:2014 testing for Type 1 Process Indicator	To demonstrate compliance to requirements specified in ISO 11140-1:2014	Device functions and transitions to blue when processed in a STERRAD® 100NX™ DUO sterilization cycle.	Pass
Testing Color Change	To demonstrate the color change of the device when used in the STERRAD® 100NX™ DUO sterilization cycle.	Color change to blue without ink bleeding	Pass
End Point Color Stability	To demonstrate the post sterilization color stability of the device after use in the STERRAD® 100NX™ DUO sterilization cycle	No significant color change after exposure to fluorescent light for a minimum of six (6) months.	Pass

Test Methodology	Purpose	Acceptance Criteria	Results
Biocompatibility and ink transfer test.	To demonstrate device and materials of construction are biocompatible with end-users and Healthcare Professionals.	Tested per ISO 11140-2:2014. Materials of construction is the same as currently cleared device. Device does not release any toxic substance in sufficient quantities to cause a health hazard, No ink migration or transfer observed with unprocessed and processed devices.	Pass.

7. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device