November 14, 2018

Crosstex/SPSmedical, A Division of Cantel Medical
Megan Skaar
Regulatory Affairs Specialist
6789 West Henrietta Road
Rush, New York 14543

Re: K181434
Trade/Device Name: SporView Rapid Read Biological Indicator SteamPlus Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: October 11, 2018
Received: October 15, 2018

Dear Megan Skaar:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -S

For Tina Kiang, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181434

Device Name

SporView Rapid Read Biological Indicator SteamPlus Test Pack

Indications for Use *(Describe)*

The SporView Rapid Read Biological Indicator SteamPlus Test Pack is intended for routine monitoring and sterilizer qualification testing of dynamic-air-removal (pre-vacuum) steam sterilization cycles at 270°F (132°C) for 4 minutes exposure time.

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.

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510(k) Summary – K181434

Manufacturer:	Crosstex/SPSmedical, a Cantel Medical Company
Address:	6789 W. Henrietta Road Rush, NY 14543 (800) 722-1529
Official Contact:	Megan Skaar Regulatory Affairs Specialist, Cantel Medical
Date:	9 November 2018
Trade Name:	SporView Rapid Read Biological Indicator SteamPlus Test Pack
Common Name:	Sterilization Biological Test Pack
Classification Name:	Sterilization Process Indicator
Product Code:	FRC
Device Class:	II
Regulation No:	Subject Device – SporView Rapid Read Biological Indicator Test Pack, 880.2800 Predicate Device – 3M Attest 3M Attest 41382 Rapid Readout Steam-Plus Process Challenge Device, 880.2800

1. Device Description

The SporView Rapid Read Biological Indicator SteamPlus Test Pack is intended for routine monitoring and sterilizer qualification testing of dynamic-air-removal (pre-vacuum) steam sterilization cycles at 270°F (132°C) for 4 minutes exposure time.

The test pack consists of multiple layers of paper cards with a SporView Rapid Read Biological Indicator, chemical process indicators and load record card. The load record card is used to record the detailed information from the sterilization cycle.

The SporView Rapid Read Biological Indicator, cleared under 510(k) K172432, is composed of a polypropylene vial containing a spore carrier and media ampoule enclosed with a vented cap.

2. Indications for Use

The SporView Rapid Read Biological Indicator SteamPlus Test Pack is intended for routine monitoring and sterilizer qualification testing of dynamic-air-removal (pre-vacuum) steam sterilization cycles at 132°C for 4 minutes exposure time.

3. Technological Characteristics Comparison Table

Table 05.1 below provides a detailed comparison between the subject, predicate and reference devices –

Table 05.1 – Predicate Device Comparison Table

Technological Characteristics	Subject Device – SporView Rapid Read Biological Indicator Test Pack	Predicate Device – 3M Attest 41382 Rapid Readout Steam-Plus Process Challenge Device (K101910)	Reference Device – SporView Plus BI Test Pack Process Challenge Device (K140620)	Comparison Summary
Intended Use	Monitor 270°F (132°C) prevacuum steam sterilization cycles for 4 minutes exposure time.	Monitor 270°F (132°C) prevacuum steam sterilization cycles with exposure time of 4 minutes.	Monitor 250°F (121°C) gravity displacement cycles and 270°F (132°C) prevacuum steam sterilization cycles for 4 minutes exposure time.	Same
Product Code	FRC	FRC	FRC	Same

FDA Regulation	21 CFR 880.2800	21 CFR 880.2800	21 CFR 880.2800	Same
Device Class	II	II	II	Same
Organism	> 90% genetic similarity to *G. stearothermophilus* ATCC™ strain 7953	> 90% genetic similarity to *G. stearothermophilus* ATCC™ strain 7953	> 90% genetic similarity to *G. stearothermophilus* ATCC™ strain 7953	Same
Viable Spore Population	1.0×10^5	1.0×10^5	1.0×10^5	Same
D-Value of Biological Indicator	Steam 132°C: 10.0 Seconds	Steam 132°C: 10.0 Seconds	Steam 132°C: 10.0 Seconds	Same
Includes 510(k) Cleared Chemical Indicators?	Yes	Yes	Yes	Same
Paper of Test Pack	Paper Index Cards	Paper Index Cards	Paper Index Cards	Same
Shelf life	12 Months	24 Months	18 Months	Similar
Storage	Controlled room temperature	Controlled room temperature	Controlled room temperature	Same
Incubation Temperature	60±2°C	60±2°C	55-60°C	Same as Predicate Device
BI Incubation Duration	3 hours	3 hours	10 hours	Same as Predicate Device
Biocompatibility	No direct patient contact	No direct patient contact	No direct patient contact	Same

The subject device – the SporView Rapid Read Biological Indicator SteamPlus Test Pack and its predicate device – 3M Attest 41382 Rapid Readout Steam-Plus Process Challenge Device are similar in that they both have the same intended use, fundamental technology and general performance. Both the subject device and the 3M Attest 41382 Rapid Readout Steam-Plus Process Challenge Device have 510(k) cleared self-contained biological indicators with a spore carrier inoculated with the same organism, *G. stearothermophilus*. The subject and predicate test packs both provide a significant challenge to the steam sterilization process.

The subject device is very similar to its reference device – the SporView Plus BI Test Pack cleared under K140620. The 510(k) cleared chemical indicators in the subject device, including the locations, of the subject test pack are identical to the reference device.

4. Summary of Non-Clinical Performance Data

The following testing has been conducted in accordance with the FDA Guidance on Biological Indicators and the FDA Guidance for Industry and FDA Staff – Premarket Notification [510(k)] Submissions for Chemical Indicators and the FDA Guidance for Industry and FDA Staff – Premarket Notification [510(k)] Submissions for Chemical Indicators. Please refer to the table below for a brief description of the subject device testing

- Non-Clinical Performance Testing of the Subject:

Performance Testing	Details and Acceptance Criteria	Results
Test Pack Performance	All test packs have complete kill in a 270°F (132°C) pre vacuum steam sterilization cycle for an exposure time of 4 minutes.	Pass
Resistance Performance	The test pack has resistance greater than or equal to the AAMI Towel Pack.	Pass
	The test pack has resistance greater than the self-contained biological indicator itself.	Pass
Chemical Indicator Performance	Testing to confirm process indicators contained in the test pack perform as intended per the FDA Guidance for Industry and FDA Staff – Premarket Notification [510(k)] Submissions for Chemical Indicators.	Pass

Performance testing demonstrates that the subject device has more resistance than the self-contained biological indicator itself and the subject device has resistance greater than or equal to the AAMI Towel Pack. There was no growth of the SCBI contained in the subject device after a full sterilization cycle.

5. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as the legally marketed predicate cleared under 510(k) K101910.