December 12, 2017

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

Re: K172432
Trade/Device Name: SporView Rapid Read Biological Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: October 31, 2017
Received: November 1, 2017

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. 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.

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.

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,

Michael J. Ryan -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)*
K172432

Device Name
SporView® Rapid Read Biological Indicator

Indications for Use *(Describe)*
The SporView® Rapid Read Biological Indicator is intended to be used with the 3M Attest Auto-Reader to monitor the effectiveness of dynamic-air-removal (prevacuum) steam sterilization cycles of 4 minutes at 132°C. The SporView Rapid Read Biological Indicator provides a final fluorescent result in 3 hours. An optional pH color change is observed after 48 hours.

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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K172432 - 510(k) Summary

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 August 2017
Trade Name:	SporView Rapid Read Biological Indicator
Common Name:	Biological Indicator
Classification Name:	Indicator, Biological Sterilization Process
Product Code:	FRC
Device Class:	II
Regulation No:	Subject Device – SporView Rapid Read Biological indicator, 880.2800 Predicate Device – 3M Attest 1292 Rapid Read Biological Indicator, 880.2800

1. Device Description

The SporView Rapid Read Biological Indicator is a self-contained biological indicator designed to be used with the 3M Attest 390 auto-reader to qualify or routinely challenge dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 270°F (132°C).

The SporView Rapid Read Biological Indicator is composed of a polypropylene vial containing a spore carrier and media ampoule enclosed with a vented cap.

Similar to the predicate device, 3M's 1292 Rapid Read-Out Biological Indicator cleared under 510(k)s K090569 and K926364, the subject device contains ≥ 10^5 viable spore population of *G. stearothermophilus*. It utilizes the α-glucosidase system, which is generated naturally within growing G. stearothermophilus. A successful steam sterilization cycle will result in no growth of *G. stearothermophilus*. A failure in the sterilization cycle creates a fluorescence change, which is detected upon incubation in the 3M 390 Attest Auto-reader. This provides an enzymatic result in

3 hours to indicate a steam sterilization process failure. The biological indicator will also detect the presence of *G. stearothermophilus* organism by a visual color change reaction. Biochemical activity of the organism will produce acid by-products that cause the media to change color after 48 hours. A visual pH color change after 48 hours also indicates a steam sterilization process failure.

2. Indications for Use

The SporView Rapid Read Biological Indicator is intended to be used with the 3M Attest 390 Auto-Reader to monitor the effectiveness of dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 132°C.

The SporView Rapid Read Biological Indicator provides a final fluorescent result in 3 hours. An optional pH color change is observed after 48 hours.

3. Comparison of Technological Characteristics with the Predicate Device

The subject device – SporView Rapid Read Biological Indicator and its predicate device – 1292 Rapid Read-Out Biological Indicator are substantially equivalent in that they both have the same intended use, fundamental technology and general performance. Both the subject device and the 3M 1292 Rapid Read Indicator have a spore carrier inoculated with the same organism, *G. stearothermophilus*. The subject and predicate BIs both utilize a α-glucosidase enzyme system, which is generated naturally within growing *G. stearothermophilus* organisms.

Table 05.1 below provides a detailed comparison between the subject and predicate device –

Table 05.1 - Predicate Device Comparison Table

Important Elements	Subject Device – SporView Rapid Read BI	Predicate Device – 3M 1292 Rapid Read-Out BI (K926364 and K090569)
Intended Use	Monitor 270°F (132°C) prevacuum steam sterilization cycles for 4 minutes.	Monitor 270°F (132°C) prevacuum steam sterilization cycles and 250°F (121°C) gravity steam sterilization cycles.
Product Code	FRC	FRC
FDA Regulation	21 CFR§ 880.2800	21 CFR§ 880.2800
Biological Indicator Design	Self-Contained Steam BI	Self-Contained Steam BI
Organism	> 90% genetic similarity to *G. stearothermophilus* ATCC™ strain 7953	> 90% genetic similarity to *G. stearothermophilus* ATCC™ strain 7953
Viable Spore Population	≥ 1.0×10^5	≥ 1.0×10^5

BI Components	Vial, cap, cap filter, base plug, glass ampoule and spore carrier	Vial, cap, cap filter, base plug, glass ampoule and spore carrier
Incubation Temperature	60±2°C	60±2°C
Incubation Duration	3 hours	3 hours
Growth Medium	Purple to yellow	Purple to yellow
D-Value	Steam 132°C: ≥ 10.0 seconds	Steam 132°C: ≥ 10.0 seconds
Z-Value	Steam 132°C: ≥ 10°C	Steam 132°C: ≥ 10°C
Minimum Survival Time & Calculation	Steam 132°C: ≥ 1 minute; D-value x (Log_{10}[viable spore population] – 2] per FDA guidance (2.10 min average)	Steam 132°C: ≥ 1 minute; D-value x (Log_{10}[viable spore population] – 2] per FDA guidance
Maximum Kill Time Calculation	D-value x (Log_{10}[viable spore population] + 4] per FDA guidance (4.98 min average)	D-value x (Log_{10}[viable spore population] + 4] per FDA guidance

4. Summary of Non-Clinical Performance Data

Medivators has conducted the following testing in accordance with the FDA Guidance on Biological Indicators to demonstrate that the SporView Rapid Readout BI meets or exceeds acceptance criteria. Please refer to the table below for a brief description of the subject device testing –

- Performance Characteristics Testing:

Performance Testing	Details and Acceptance Criteria	Results
Viable Spore Population Assay	Assay to demonstrate the spore population of the BI meets specification of ≥ 10^5.	Pass
Resistance Characteristics Testing	Resistance characteristics of the BI in the intended steam 132°C sterilization process and cycle using a resistometer must be: D-Value: ≥ 10 seconds Z-Value: ≥ 10°C Survival Time: ≥ 1 minute	Pass
Carrier and Primary Packaging Materials	Carrier and primary packaging materials must not have inhibitory effects on the growth of test organisms of the BI after sterilization.	Pass
Holding Time Assessment	The 7 day holding time must have no effects on the performance of the subject BI.	Pass

Growth Promotion and Media Suitability	The media of the biological indicator must support growth and recovery to be suitable.	Pass
Reduced Incubation Time	Verification of 3 hour fluorescent and 48 hour biological readout per FDA's Validation of Reduced Incubation Protocol.	Pass
Verification of Full and Fractional Cycle	Partial kill achieved after a fractional cycle and full biological inactivation after a full cycle in a marketed sterilizer.	Pass
3M 390 Auto-Reader Compatibility Testing	Evaluation that the compatibility of the SporView Rapid Read BI and 3M 390 Auto-Reader system such that the auto-reader reads and displays accurate results and alarms appropriately upon BI removal.	Pass

- Shelf Life Testing: Verification of the viable spore population, resistance characteristics and media stability at the end of the shelf life.

5. Conclusion

The subject device effectively monitors dynamic-air-removal (pre-vacuum) steam sterilization cycles of 4 minutes at 132°C. The SporView Rapid Read Biological Indicator is substantially equivalent to predicate device 3M 1292 Rapid Read-Out Biological Indicator originally cleared in 510(k) K090569.