March 24, 2021

TSO3 Inc., Now a part of Stryker
Karan Modi, MS, RAC
Staff Regulatory Affairs Specialist
1941, Stryker Way
Portage, Michigan 49002
USA

Re: K203560
Trade/Device Name: STERIZONE VP4 Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: February 19, 2021
Received: February 23, 2021

Dear Karan Modi:

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,

for Clarence W. Murray, III, PhD.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203560

Device Name
STERIZONE® VP4 Test Pack

Indications for Use *(Describe)*
The STERIZONE® VP4 Test Pack is intended to be used for routine monitoring of the STERIZONE® VP4 Sterilizer cycle (Cycle 1) and for the performance validation of the STERIZONE® VP4 Sterilizer system.

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.

K203560 – 510(k) Summary

K203560

1. Submitter

510(k) Owner:	TSO3 Inc., Now a part of Stryker 2505, avenue Dalton Québec (Québec) G1P 3S5 Canada
FDA Establishment Registration Number:	3004148947
Contact Person:	Karan Modi, MS, RAC Staff Regulatory Affairs Specialist Stryker Instruments 1941 Stryker Way Portage, Michigan 49002 USA P 269 888 0305 karan.modi@stryker.com
Date Submitted:	March 24, 2021

2. Subject Device Name

Trade Name:	STERIZONE® VP4 Test Pack
Common Name:	Biological Indicator (Test Pack)
Classification:	Class II
Classification Product Code:	FRC
Classification Name:	Indicator, Biological Sterilization Process
Classification Regulation:	21CFR 880.2800
Review Panel:	General Hospital
Submission Type:	Traditional 510(k)

K203560 – 510(k) Summary

3. Legally Marketed Predicate Device

Predicate Device	
STERIZONE® VP4 Test Pack	K141580
Reference Device	
Terragene Bionova® SCBI (BT96)	K191021

4. Device Description

The STERIZONE® VP4 Test Pack is a Process Challenge Device (PCD) designed to have greater resistance than the worst-case sterilization load of the STERIZONE® VP4 Sterilizer. The STERIZONE® VP4 Test Pack is intended to simulate products to be sterilized and to constitute a defined challenge to the sterilization process and used to assess the effective performance of the process.

The STERIZONE® VP4 Test Pack cleared under K141580 contained a biological indicator (STERIZONE® BI+) which required 18 hours of incubation time. This Traditional 510(k) submission aims to qualify an additional biological indicator - Terragene's Bionova® BT96 (hereinafter referred to as "BT96") within the STERIZONE® VP4 Test Pack (hereinafter referred to as "Test Pack"). BT96 is a rapid biological indicator with 30 mins of incubation time and is cleared under K191021 for monitoring the effectiveness of sterilization processes that use vaporized hydrogen peroxide as the primary sterilant, including the STERIZONE® VP4 Sterilizer. The Test Pack with STERIZONE® BI+ cleared under K141580 will continue to be an option for customers to use.

The STERIZONE® VP4 Test Pack (subject device) is composed of a Self-contained Biological Indicator (the Terragene's Bionova® BT96), a 10 mL syringe and its plunger, and a diffusion restrictor. A STERIZONE® CI+ Chemical Indicator is also added, external to the syringe, to allow differentiating processed from unprocessed test packs. All components of the Test Pack are single-use, disposable items.

K203560 – 510(k) Summary

5. Intended Use/Indications for use

The STERIZONE® VP4 Test Pack is intended to be used for routine monitoring of the STERIZONE® VP4 Sterilizer cycle (Cycle 1) and for the performance validation of the STERIZONE® VP4 Sterilizer system.

6. Comparison of Technological Characteristics with the Predicate Device

The following table identifies technological characteristics shared between the Predicate and Subject device:

Table 1. Comparison of the subject and the predicate (K141580) STERIZONE® VP4 Test Pack devices

Features	STERIZONE® VP4 Test Pack (Predicate Device- K141580)	STERIZONE® VP4 Test Pack (Subject Device)
Product description	A Self-contained BI, and a syringe with diffusion restrictor for holding the BI during the sterilization cycle, along with a process chemical indicator.	Same
Picture of the device		
Intended Use	Routine monitoring of the STERIZONE® VP4 Sterilizer cycle and performance validation of the STERIZONE® VP4 Sterilizer system	Same
Indications for Use	The STERIZONE® BI+ Self-contained Biological Indicator (SCBI) is intended for routine monitoring of the STERIZONE® VP4 Sterilizer, which offers a single pre-set sterilization cycle ("Cycle 1"). The SCBI should only be used in a Test Pack configuration to monitor Cycle 1. The SCBI placed within the STERIZONE® VP4 Test Pack monitors exposure to both vaporized hydrogen peroxide (H2O2 or VHP) and ozone (O3) which are both used in the STERIZONE® VP4 Sterilizer. The STERIZONE® VP4 Test Pack is intended to have equivalent to greater resistance than worst case devices and loads in any load configuration.	The STERIZONE® VP4 Test Pack is intended to be used for routine monitoring of the STERIZONE® VP4 Sterilizer cycle (Cycle 1) and for the performance validation of the STERIZONE® VP4 Sterilizer system.

K203560 – 510(k) Summary

Features	STERIZONE® VP4 Test Pack (Predicate Device- K141580)	STERIZONE® VP4 Test Pack (Subject Device)
	The STERIZONE® VP4 Test Pack is a device composed of the STERIZONE® BI+ Self-contained Biological Indicator (TSO3 product code 42602, including crusher), a 10 mL syringe and its plunger, and a diffusion restrictor (sold in the form of a kit - TSO3 product code: 44020). An external STERIZONE® CI+ Chemical Indicator (TSO3 product code 43810) is also added to allow differentiating processed from unprocessed test packs. All components of the Test Pack are single-use, disposable items. The STERIZONE® VP4 Test Pack is constructed by first inserting the STERIZONE® BI+ Self-contained Biological Indicator inside the syringe, with the SCBI cap facing to the Luer-lock of the syringe. The plunger is then inserted to the 10 mL mark of the syringe. The diffusion restrictor is screwed to the Luer-lock of the syringe. The chemical indicator is then inserted in the opening between the plunger and the syringe. The test pack is then placed within the load on the upper shelf of the STERIZONE® VP4 Sterilizer loading rack. After processing, the SCBI is retrieved from the test pack. The SCBI is intended to provide users with a means to assess spore kill by the STERIZONE® VP4 Sterilizer. A "no growth" result from the SCBI after 18 hours of incubation indicates that the process achieved the conditions necessary to kill at least 1×10^6 viable spores of *Geobacillus stearothermophilus* (6 logs) on the SCBI inoculated stainless steel carrier.	
Contraindication	• Do not use in a system other than the STERIZONE® VP4 Sterilizer. • Do not reuse any test pack component after it has been processed in the STERIZONE® VP4 Sterilizer.	Same
Sterilizer to be monitored by the test pack	STERIZONE® VP4 Sterilizer	Same
Biological indicator	STERIZONE® BI+ Self-contained Biological Indicator (K141580)	Terragene Bionova® SCBI (BT96) (K191021)

K203560 – 510(k) Summary

Features	STERIZONE® VP4 Test Pack (Predicate Device- K141580)	STERIZONE® VP4 Test Pack (Subject Device)
	Geobacillus stearothermophilus ATCC 7953 spores	*Geobacillus stearothermophilus* ATCC 7953 spores
Holder	Syringe and plunger– 10 mL Becton-Dickinson (BD) plastic syringe with Luer-Lok™ connector and its plunger	Same
Diffusion restrictor	18 gauge (1.02 mm diameter), 2-inch (50.8 mm) long polytetrafluoroethylene (PTFE) cannula with Luer-lock attachment	Same
Chemical Indicator	STERIZONE® CI+ Chemical Indicator	Same
Resistance characteristics	Demonstrated to have equivalent or greater resistance than the worst case devices and loads in any load configuration. Demonstrated to be more resistant than the half-cycle, including exposure to hydrogen peroxide and ozone.	Same

The intended use of the modified device, as described in the labeling, has not changed as a result of the modification.

The STERIZONE® VP4 Test Pack components are identical to its original filing with the exception of the Self-Contained Biological Indicator.

- Bionova® BT96 Super Rapid Readout Biological Indicator from Terragene (K191021)
- A diffusion restrictor (same as predicate): PTFE canula of 18 gauge and 2 inches (5.1 cm) in length (with a Luer-lock connector) (K141580)
- A plastic syringe (same as predicate): A 10 mL Becton Dickinson (BD) plastic syringe with Luer-Lok™ tip (K141580)
- A chemical indicator (same as predicate): STERIZONE® CI+ Chemical Indicator (K141580 and K141698)

The difference in the self-contained biological indicator between the subject and predicate device was considered in relation to the substantial equivalence determination:

The predicate Test Pack (PCD) contains the STERIZONE® BI+ Self-contained Biological Indicator (BI+) which was cleared under K141580. The subject Test Pack

(PCD) contains the Bionova® BT96 Super Rapid Readout Biological Indicator from Terragene. The BT96 biological indicator is cleared for monitoring the effectiveness of STERIZONE® VP4 Sterilizer under K191021 and is therefore used in this submission as a reference device. Similar to the BI+, the BT96 is a self-contained biological indicator inoculated with at least 10^6 Geobacillus stearothermophilus viable bacterial spores. The qualification of BT96 as a biological challenge device for use within the Test Pack would provide a rapid readout option to the users. The BT96 biological indicator offers rapid readout (30 mins incubation time) compared to 18 hours with the current BI+.

7. Performance Testing - Bench

The performance of the subject STERIZONE® VP4 Test Pack (using BT96) was evaluated in accordance with FDA guidance document for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions," issued on October 4, 2007. All results from testing meet the predetermined acceptance criteria.

The following performance data were provided in support of the substantial equivalence determination:

Table 2. Summary of Nonclinical Testing:

Test Name	Test Purpose	Test Acceptance Criteria	Subject Device Test Result
Half-cycle Survivability	Determine if the SCBI, when used within the Test Pack, can provide a resistance to the sterilization process that is equal to or greater than the most difficult item routinely processed in the sterilizer, per ISO 14937, ISO 11138-7 and the Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission.	The SCBI in the Test Pack must show growth at half-cycle in all the limit parameter loads tested.	The SCBI in the Test Pack showed growth at half-cycle in all the limit parameter loads tested.
Full cycle inactivation	Determine if the SCBI used within the Test Pack can repeatedly and consistently show an inactivation point in the second half of the sterilization cycle.	The SCBI in the Test Packs must demonstrate a survival ratio of 0% at least at the full cycle using the worst-case challenge load.	The SCBI in the Test Pack shows survival ratio of 0% in the second half of the sterilizer cycle, thus shows total inactivation by the end of a full cycle.
Increased resistance	Determine if the use of the Test Pack provides a greater challenge to the process than the BI itself, per Guidance for Industry and Staff – Biological Indicator (BI) Premarket Notification [510(k)] Submission.	The SCBI in the VP4 Test Pack must show a higher survival ratio than its naked counterpart.	When exposed to the same partial cycles, the SCBI in the Test Pack showed growth while the naked SCBI was fully inactivated.

K203560 – 510(k) Summary

8. Conclusion

The performance testing demonstrates that the subject STERIZONE® VP4 Test Pack is substantially equivalent to the identified predicate STERIZONE® VP4 Test Pack (K141580).