July 19, 2019

TSO3 Inc
% Cynthia Pritchard
CEO
BioTechnology Transfer, LLC
1016 Tobiano Lane
Raleigh, North Carolina 27614

Re: K190260
Trade/Device Name: STERIZONE® VP4 Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: PJJ
Dated: June 24, 2019
Received: June 25, 2019

Dear Cynthia Pritchard:

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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*

Device Name

STERIZONE® VP4 Sterilizer

Indications for Use (*Describe*)

The STERIZONE® VP4 Sterilizer is intended for use in terminal sterilization of cleaned, rinsed, and dried metal and non- metal reusable medical devices in health care facilities.

The single pre-set cycle of the STERIZONE® VP4 Sterilizer uses hydrogen peroxide and ozone. The injection of vaporized hydrogen peroxide is followed by the injection of ozone, which reacts with residual hydrogen peroxide to form hydroxyl radicals.

Sterilization efficacy was demonstrated using a representative sample of one or more device types and packaging, in nine separate validation loads, as described in Table 1 [refer to continuation pages 2 - 4 of this form]. The load to be processed should be maintained between 20°C to 26°C (68°F to 78°F). Total load weight shall not exceed 75 lb, inclusive of the containers/packaging weight but excluding the 25 lb loading rack.

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."

Table 1. Description of the nine validation loads

Validation load #	**Load description**	**Load weight** [Excluding the 25 lb loading rack]
1	Validation load #1 consisted of **general medical instruments**, representing the following geometries: • Clamp • Serrated surface • Box-lock • Handle • Button • Pivot hinge • Stopcock Type of packaging used: wrapped plastic tray, including silicone mats and brackets, and Pouch General medical instruments were spread out over three trays, six pouches and one wrapped instrument.	11 lb
2	Validation load #2 consisted of **general medical instruments**, representing the following geometries: • Gliding mechanism • Hinges and screws • Serrated surface • Luer-lock • Spring • Rigid non-lumen scopes Type of packaging used: wrapped plastic and aluminum tray, including silicone mats and brackets, rigid aluminum container and Pouch General medical instruments were spread out over one container, three trays, and six pouches.	20 lb
3	Validation load #3 consisted of **three single-channel flexible endoscopes** (Ureteroscope) with inside diameter of 1.0 mm and length of 850 mm, packaged individually in wrapped trays or containers, including appropriate silicone brackets or mats. Eight general medical instruments, each packaged in a pouch, were added.	23 lb

Validation load #	Load description	Load weight [Excluding the 25 lb loading rack]
4	Validation load #4 consisted of up to **15 rigid or semi-rigid channeled instruments in the presence of other packaged medical devices**. Three double channel semi-rigid endoscopes (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. Additional rigid channel instruments or stainless steel rigid lumens were added to each package. Two additional general medical instruments, each packaged in a pouch, were added.	19 lb
5	Validation load #5 consisted in **two single channel flexible endoscopes;** one Ureteroscope with inside diameter of 1.0 mm and length of 850 mm, and a Bronchoscope with inside diameter of 1.8 mm and length of 830 mm, and **one** double channel semi- rigid endoscope (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm), packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. No additional item was added.	21 lb
6	Validation load #6 consisted of **general medical instruments**, representing the following geometries: • Distal end (swivel parts) • Hinge with screw • Cannula General medical instruments packaged in one aluminum sterilization container.	9 lb
7	Validation load #7 consisted of **general medical instruments**, representing the following geometries: • Box-lock hinge • Pivot hinge • Luer-lock General medical instruments, spread out over three aluminum sterilization containers, each weighing 25 lb.	75 lb

Validation load #	Load description	Load weight [Excluding the 25 lb loading rack]
8	Validation load #8 consisted of **two double-channel flexible endoscopes** (Ureteroscope) with inside diameter of 1 mm and lengths of 850 and 989 mm; and **one single-channel** flexible endoscopes (Ureteroscope) with inside diameter of 1 mm and length of 850 mm, packaged individually in wrapped plastic sterilization trays, including appropriate silicone brackets or mats.	16 lb
9	Validation load #9 consisted of **one multi-channel flexible endoscope,** with no more than 4 channels (Video Colonoscope), with inside diameters of 1.2 mm or more and lengths of 1955 mm or less, or inside diameters of 1.45 mm or more and lengths of 3500 mm or less; packaged in aluminum sterilization container.	17 lb

510(k) Summary

Applicant Name and Address

TSO3 Inc.
2505, avenue Dalton
Québec, QC G1P 3S5
Canada

Contact Person, Telephone, Fax

Sandy Cliche, Director, Regulatory Affairs and Quality Assurance
Phone: (418) 651-0003 ext. 252
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Date of Preparation

24 June 2019

Trade Name

STERIZONE® VP4 Sterilizer

Common Name

Dual Sterilant Sterilizer

Classification Name

Regulation Number and Regulation Description: 21 CFR 880.6860; Ethylene oxide gas sterilizer
Product Code and Device Name: PJJ; Two or more sterilant sterilizer
Technical Method: Dual sterilant sterilizer using hydrogen peroxide and ozone as the sterilant

Legally Marketed Predicate Device Name

STERIZONE® VP4 Sterilizer (K173694)

Device Description

The STERIZONE® VP4 Sterilizer (VP4) is a self-contained stand-alone device, using vaporized hydrogen peroxide and ozone in a multiphase process. The VP4 offers a single sterilization cycle intended for general instruments, flexible endoscopes (including single, dual, and multi-channel devices), and rigid-channel devices (including single-channel and double-channel rigid endoscopes).

The changes to the sterilizer are component changes that were made to extend the use life of the hydrogen peroxide vaporization block. These changes include: 1] anodization of the hydrogen peroxide vaporization block, and 2] a reduction of the stabilizer concentration in the hydrogen peroxide solution.

Indications for Use

The STERIZONE® VP4 Sterilizer is intended for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in health care facilities. The single pre-set cycle of the STERIZONE® VP4 Sterilizer uses hydrogen peroxide and ozone. The injection of vaporized hydrogen peroxide is followed by the injection of ozone, which reacts with residual hydrogen peroxide to form hydroxyl radicals.

Sterilization efficacy was demonstrated using a representative sample of one or more device types and packaging, in nine separate validation loads, as described in Table 1. The load to be processed should be maintained between 20°C to 26°C (68°F to 78°F). Total load weight shall not exceed 75 lb, inclusive of the containers/packaging weight but excluding the 25 lb loading rack.

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2	Validation load #2 consisted of **general medical instruments**, representing the following geometries: • Gliding mechanism • Hinges and screws • Serrated surface • Luer-lock • Spring • Rigid non-lumen scopes Type of packaging used: wrapped plastic and aluminum tray, including silicone mats and brackets, rigid aluminum container and Pouch General medical instruments were spread out over one container, three trays, and six pouches.	20 lb
3	Validation load #3 consisted of **three single-channel flexible endoscopes** (Ureteroscope) with inside diameter of 1.0 mm and length of 850 mm, packaged individually in wrapped trays or containers, including appropriate silicone brackets or mats. Eight general medical instruments, each packaged in a pouch, were added.	23 lb
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5	Validation load #5 consisted in **two single channel flexible endoscopes;** one Ureteroscope with inside diameter of 1.0 mm and length of 850 mm, and a Bronchoscope with inside diameter of 1.8 mm and length of 830 mm, and **one** double channel semi- rigid endoscope (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm), packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. No additional item was added.	21 lb

Validation load #	Load description	Load weight [Excluding the 25 lb loading rack]
6	Validation load #6 consisted of **general medical instruments**, representing the following geometries: • Distal end (swivel parts) • Hinge with screw • Cannula General medical instruments packaged in one aluminum sterilization container.	9 lb
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9	Validation load #9 consisted of **one multi-channel flexible endoscope,** with no more than 4 channels (Video Colonoscope), with inside diameters of 1.2 mm or more and lengths of 1955 mm or less, or inside diameters of 1.45 mm or more and lengths of 3500 mm or less; packaged in aluminum sterilization container.	17 lb

Technological Characteristics

A comparison between the subject and predicate devices is provided [Table 2].

Table 2: General comparison of technical specifications, technology, and indications for use between the STERIZONE® VP4 Sterilizer and the predicate device

	Predicate STERIZONE VP4 Sterilizer K173694			Subject STERIZONE VP4 K190260	
Intended Use	Terminal sterilization of reusable medical devices in health care facilities			Same	
General Indication for Use	See Above			Same	
Lumen claims		Inner Diameter	Lumen Length	Inner Diameter	Lumen Length
	Single Channel Flexible Endoscope	≥ 1mm	≤ 850 mm	Same	Same
	Single & Double Channel Flexible Endoscope	≥ 1 mm	≤ 989 mm	Same	Same
	Multi-channel Flexible Endoscope (Video colonoscope/gastroscope – 4 channels total)	≥ 1.2 mm ≥ 1.45 mm	≤ 1955 mm ≤ 3500 mm	Same	Same
	Rigid Single & Double Channel Endoscope	≥ 0.7 mm	≤ 500 mm	Same	Same
Sterilant	Vaporized Hydrogen Peroxide/Ozone			Same	
H_2O_2 Concentration by Weight	50%			Same	
Number of Sterilization Cycles	One (“Cycle 1”)			Same	
Critical Process Parameters	Differential Chamber Pressure (ΔP) and Load Temperature			Same	
General Physical Process Parameters	Wall temperature, vaporization temperature, exposure times, flow rates, ozone concentration, component temperatures			Same	

Chamber Volume	125L	Same

Software Control	Omron PLC	Same
H_2O_2 Vaporization Block	6061 Aluminum H_2O_2 Vaporization Block Non-anodized	6061 Aluminum H_2O_2 Vaporization Block with anodization surface treatment
Hydrogen Peroxide Solution	Durox® Grade H_2O_2 50-50.8% Stabilizers	Semiconductor Grade H_2O_2 50-50.8% Same stabilizers, but a lower concentration

The proposed changes to the sterilizer were for component changes. These changes were made to extend the use life of the hydrogen peroxide vaporization block. These changes include: 1] anodization of the hydrogen peroxide vaporization block, and 2] a reduction of the stabilizer concentration in the hydrogen peroxide solution.

Summary of Non-Clinical Testing:

Description of performance testing:

The modified STERIZONE® VP4 Sterilizer has been designed, constructed and tested to meet the safety and performance requirements of various North American safety codes and standards. The modified STERIZONE® VP4 Sterilizer complies with the applicable portions of the following standards:

- Canadian Standard Association (CSA) Standard C22.2 No 61010-1
- Underwriters Laboratory Standard UL 61010-1
- Federal Communication Commission (FCC) Part 18 / EN 55011
- International Electrotechnical Commission (IEC) Standard IEC 61326-1
- International Electrotechnical Commission (IEC) Standard 61010-1 :2010, 61010-2-040

Sterility testing of directly inoculated medical devices was conducted employing an overkill approach in the modified sterilizers to demonstrate achievement of a sterility assurance level (SAL) of 10^{-6}. In each case, all parameters of each part of the test series met acceptance criteria.

The modification did not in any way impact the biocompatibility of the materials of the sterilized devices, since the materials sterilized, and the sterilant residuals, have not changed. The verification tests performed to determine the concentration of post-sterilization H_2O_2 residuals on materials sterilized with the STERIZONE® VP4 Sterilizer equipped with the proposed anodized H_2O_2 vaporization block and the Semiconductor-grade H_2O_2 solution were tested under worst-case conditions.

A Failure Mode Effects Analysis (FMEA) has been conducted on the entire system of the STERIZONE® VP4 Sterilizer to ensure safety features and control redundancies have been implemented in the design and will be maintained during the manufacturing, installation,

maintenance and servicing of the sterilizers. No changes to the user manual, labeling, or software were required.

Description of the Sterilization Validation Activities:

The modified STERIZONE® VP4 Sterilizer underwent performance validation testing using the "overkill" approach to demonstrate the effectiveness of the process in accordance with ANSI/AAMI/ISO 14937. Testing on directly inoculated medical devices was conducted employing half-cycle to demonstrate achievement of a sterility assurance level (SAL) of 10^{-6}. This process has been demonstrated to achieve a sterility assurance level of 10^{-6} for terminal sterilization of packaged reusable medical devices.

Performance Testing Conclusion:

New test data have been generated in accordance with the FDA Sterilizer Guidance documents and applicable standards, to ensure that the sterilizer performance and other specifications meet TSO_3 acceptance criteria.

Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the STERIZONE® VP4 Sterilizer is as safe, as effective and performs as well as or better than the legally marketed predicate device (K173694).