March 13, 2018

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

Re: K173694
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: February 2, 2018
Received: February 15, 2018

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. 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)*
K173694

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. 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.

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Table 1. Description of the nine validation loads

Validation load #	Load description	Load weight[1]
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[1]
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 channeled 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.	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 weighting 25 lb.	75 lb
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

Validation load #	Load description	Load weight[1]
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 or more and lengths of 1955 mm or less, or 1.45 or more and lengths of 3500 mm or less; packaged in aluminium sterilization container.	17 lb

[1]Excluding the 25-lb loading rack

510(k) Summary
K173694

General Information:	Owner's Name:	TSO_3 Inc.
	Address:	TSO_3 Inc. 2505, Avenue Dalton Quebec, QC G1P 3S5, Canada
	Contact Person:	Alexandre Jokic TSO_3, Inc. Director Regulatory Affairs and Quality Assurance
	Address:	TSO_3 Inc. 2505, Avenue Dalton Quebec, QC G1P 3S5, Canada
	Telephone:	418-651-0003 ext. 287
	Fax Number:	418-653-5726
Subject Device:	Trade Name:	STERIZONE® VP4 Sterilizer
	Common Name:	Dual sterilant sterilizer
	Product Code:	PJJ
	FDA Regulation:	21 CFR 880.6860
	Device Classification:	Class II
Predicate Device:	Trade Name:	STERIZONE® VP4 Sterilizer
	Common Name:	Dual sterilant sterilizer
	Product Code:	PJJ
	FDA Regulation:	21 CFR 880.6860
	Device Classification:	Class II
	Premarket Notification:	K153689

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.

Table 1: Description of the validation loads

Validation load #	Load description	Load weight[1]
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
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 weighting 25 lb	75 lb

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

[1]Excluding the 25-lb loading rack

Device Description: The STERIZONE® VP4 Sterilizer is a versatile low temperature sterilizer using two sterilants (vaporized hydrogen peroxide [H_2O_2] and ozone [O_3]) in a multi-phase process to sterilize reusable medical instruments up to a maximum load of 75 lb. In contrast to the sterilization processes using H_2O_2 only and having multiple cycles, the STERIZONE® VP4 Sterilizer enables the sterilization of a wider range of instruments and load configuration with only one preset cycle. The dynamic system to distribute the sterilant ensures an adequate supply of the sterilant through multiple successive pulsed injections that adapt to the different load conditions (size, weight and temperature). The STERIZONE® VP4 Sterilizer offers a unique preset sterilization cycle (Cycle 1) to sterilize a wide range of loads consisting of general instruments, flexible endoscopes with one channel, double channels and multi-channels, and devices with rigid and semi-rigid channels, including rigid endoscopes with single or double channels.

Technological Characteristics Comparison Table

Device Trade Name	Predicate STERIZONE VP4 Sterilizer K153689	STERIZONE VP4 Sterilizer (with air vent option) K173694
Device Class	Class II	Same
Product Code / Regulation	PJJ	Same
Regulation Name	Dual sterilant sterilizer	Same
Indications for Use	Terminal sterilization of reusable medical devices in health care facilities	Same

		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 (colonoscope – the FDA considers this a 4-channel device)	≥ 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	1 (“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	
Ventilation gas	≥94% oxygen			Ambient air	
Component changes	NA			Installation kit [filter; valve]	

Cycle Process Parameters Comparison Table

Device Trade Name			Predicate STERIZONE® VP4 Sterilizer K153689	STERIZONE® VP4 Sterilizer (Air vent option)
Phase	**Cycle Steps**	**Controlled parameter**	**Value**	**Value**
	Pre-conditioning	Pressure	1 Torr	Same
Phase 1	*Dynamic H_2O_2 exposure*	Differential pressure of 125-280 Solution vaporized and injected	19 Torr	Same
	H_2O_2 reduction:	Ozone injection	2 mg/L	Same
		Ozone dwell	5 min.	Same

	Evacuation	Pressure	1 Torr	Same
Phase 2	*Dynamic H_2O_2 exposure*	Differential pressure of 125-280 Solution vaporized and injected	19 Torr	Same
	H_2O_2 reduction:	Ozone injection	2 mg/L	Same
		Ozone dwell	5 min.	Same
	Evacuation	Pressure	1 Torr	Same
	Ventilation	depressurization	Atmospheric pressure using pressurized O_2	Atmospheric pressure using ambient air

Labeling:

There has been no change to the intended use. There have been no changes to warnings, contraindications, or precautions in comparison to the device cleared in K153689. The mode of operation remains the same. This new feature does not impact the device usability in any way.

Statement on Fundamental Technology:

These changes do not in any way alter the fundamental scientific technology upon which the device is based. The operating principle has not changed. The sterilizer incorporates the same basic design. The sterilization cycle is identical to that of the predicate. The software has not changed. The only changes made are mechanical component changes, to allow the use of ambient air, instead of pressurized oxygen, for final ventilation of the chamber.

Biocompatibility

The purpose of the biocompatibility testing was to provide evidence of the biological safety of materials commonly found in medical devices after being processed in the STERIZONE® VP4 Sterilizer. Materials were tested in accordance with ISO 10993-1:2009 (Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process) to determine which tests are necessary to demonstrate biocompatibility of the patient-contacting materials present in the finished device.

- Cytotoxicity (in vitro)
- Hemocompatibility
- Intracutaneous
- Sensitization reactivity
- Irritation (Ocular)
- Acute systemic toxicity

This design change 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.

Microbiological, Functional and Compatibility Testing

Verification test results demonstrated that residual sterilants present on the selected materials were within the acceptance criteria already cleared for the STERIZONE® VP4 sterilizer.

Safety Testing

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

- IEC 61010-1 2004 Safety requirement for measurement, control and laboratory use - Part 1: General
- IEC 61010-2-040 2005 Safety requirement for measurement, control and laboratory use Part 2 particular requirements for sterilizers and washer-disinfectors used to treat medical materials
- IEC 61326-1: 2012 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- Federal Communication Commission (FCC) Part 18 / EN 55011

Risk Management

There was one potential risk [sterilant residual levels] identified due to the change of gas for final ventilation. However, verification testing showed that residuals were within acceptance criteria for previously cleared versions of the STERIZONE VP4. All potential hazards and failure modes identified during the design and development processes were addressed and did not impact the existing labeling. The risk management activities included application FMEA, design FMEA and manufacturing process FMEA.

Conclusion

The results of the verification/validation tests and the risk analyses have demonstrated that the STERIZONE® VP4 Sterilizer (air vent option; K173694) is substantially equivalent to the STERIZONE® VP4 Sterilizer (K153689).