U.S. FOOD & DRUG ADMINISTRATION

May 9, 2018

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

Re: K172191
Trade/Device Name: STERIZONE VP4 Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: PJJ
Dated: March 16, 2018
Received: April 9, 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,

Geeta K.
Pamidimukkala -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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K172191

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 lbs, inclusive of the containers/packaging weight but excluding the 25 lbs loading rack.

**Table 1. Description of the nine validation loads**

| Validation load # | Load description | Load weight[1]<br>[1]Excluding the 25 lb loading rack |
|---|---|---|
| 1 | Validation load #1 consisted of general medical instruments, representing the following geometries:<br>• Clamp<br>• Serrated surface<br>• Box-lock<br>• Handle<br>• Button<br>• Pivot hinge<br>• Stopcock<br>Type of packaging used: wrapped plastic tray, including silicone mats and brackets, and Pouch<br>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:<br>• Gliding mechanism<br>• Hinges and screws<br>• Serrated surface<br>• Luer-lock<br>• Spring<br>• Rigid non-lumen scopes<br>Type of packaging used: wrapped plastic and aluminum tray, including silicone mats and brackets, rigid aluminum container and Pouch<br>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 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 |

| Validation load # | Load description | Load weight[1]<br>[1]Excluding the 25 lb loading rack |
|---|---|---|
| 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:<br>• Distal end (swivel parts)<br>• Hinge with screw<br>• Cannula<br>General medical instruments packaged in one aluminum sterilization container. | 9 lb |
| 7 | Validation load #7 consisted of general medical instruments, representing the following geometries:<br>• Box-lock hinge<br>• Pivot hinge<br>• Luer-lock<br>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 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 |

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.***

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# 510(k) Summary

**Applicant's Name and Address**
$TSO_3$ Inc.
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Canada

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**Date of Preparation**
May 7, 2018

**Trade Name**
STERIZONE® VP4 Sterilizer

**Common Name**
Vaporized Hydrogen Peroxide Sterilizer

**Classification Name**
Ethylene Oxide Gas Sterilizer
Class II (as per 21CFR, part 880.6860 equivalent device)
Product Code:  PJJ

**Legally Marketed Equivalent Device Name(s)**
STERIZONE® VP4 Sterilizer (K141163 and K153392)
K141163 - Primary Predicate

## 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).

Lumen claims for the VP4 have been expanded to include double and multiple-channel devices with no more than four channels.

## 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.

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| 2 | Validation load #2 consisted of general medical instruments, representing the following geometries:<br>• Gliding mechanism<br>• Hinges and screws<br>• Serrated surface<br>• Luer-lock<br>• Spring<br>• Rigid non-lumen scopes<br>Type of packaging used: wrapped plastic and aluminum tray, including silicone mats and brackets, rigid aluminum container and Pouch<br>General medical instruments were spread out over one container, three trays, and six pouches. | 20 lb |
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| Validation load # | Load description | Load weight[1] [1]Excluding the 25 lb loading rack |
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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 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 |

## Performance Data

### Safety

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: 2004
- Underwriters Laboratory Standard UL 61010-1: 2004
- Federal Communication Commission (FCC) Part 18 / EN 55011
- International Electrotechnical Commission (IEC) Standard IEC 61326-1: 2012
- International Electrotechnical Commission (IEC) Standard 61010-1 :2010, 61010-2-040: 2005

A Fault Tree Analysis and Mitigation (FTA-MIT) and a Failure Mode Effects and Criticality Analysis (FMECA) 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.

The software controls of the modified STERIZONE® VP4 Sterilizer have undergone verification and validation testing in accordance with FDA's Guidance entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this sterilizer was considered "moderate risk". Testing was completed with no unresolved anomalies.

### Effectiveness

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 be effective for terminal sterilization of packaged reusable medical devices.

**Substantial equivalence**

The STERIZONE® VP4 Sterilizer, with the expanded flexible lumen claims, is substantially equivalent to the predicate STERIZONE® VP4 Sterilizer (K141163). The design, materials, and functions of the sterilizers are identical. Furthermore, the intended use and general indications for use are identical. Changes to the lumen claims do not raise different questions regarding safety and effectiveness. A comparison between the two devices is provided in Table 2.

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

| | ***PREDICATE*** **STERIZONE® VP4 Sterilizer K141163 and K153392** | | | **STERIZONE® VP4 Sterilizer with expanded flexible lumen claims** | |
|---|---|---|---|---|---|
| Intended Use | Terminal sterilization of reusable medical devices in health care facilities | | | Same | |
| General Indication for Use | Sterilization of both metal and nonmetal medical devices. Sterilization of instruments, which have diffusion-restricted spaces, such as hinged portions of forceps and scissors. Processing of medical devices having rigid and flexible channels with limitations in materials, dimensions and number of devices. | | | 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 |
| | Multi-channel Flexible Endoscope (Video colonoscope/gastroscope – 4 channels total) | | | ≥ 1.2 mm<br>≥ 1.45 mm | ≤ 1955 mm<br>≤ 3500 mm |
| | Rigid Single & Double Channel Endoscope | ≥ 0.7 mm | ≤ 500 mm | Same | Same |
| Sterilant | Vaprorized 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 |

## Conclusion

The STERIZONE® VP4 Sterilizer, with the expanded flexible lumen claims, is substantially equivalent to the identified predicate device, the STERIZONE® VP4 Sterilizer.