DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 24, 2016

TSO_3 Inc.
c/o Thomas Richards, Ph.D.
Consultant
IM3, Inc.
7720 NE Hwy 99, Suite D #110
Vancouver, Washington 98665

Re: K153392
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 22, 2016
Received: February 24, 2016

Dear Dr. Richards:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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)*

K153392

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 seven 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 seven validation loads

Validation load #	Load description	Load weight[1] [1]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

Validation load #	Load description	Load weight[1] [1]Excluding the 25 lb loading rack
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
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

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."

510(k) Summary

Applicant's Name and Address
TSO_3 Inc.
2505, avenue Dalton
Quebec, QC G1P 3S5
Canada

Contact Person, Telephone, FAX
Alexandre Jokic, Director, Regulatory Affairs and Quality Assurance
Tel: (418) 651-0003 ext. 287
FAX: (418) 653-5726
Email: ajokic@tso3.com

U.S. Contact
IM3, Inc.
Contact: Thomas Richards, Ph.D.
Phone: 503-415-0250
Email: tomami20x@gmail.com

Submission Date
November 20, 2015

Trade Name
STERIZONE® VP4 Sterilizer

Common Name
Vaporized Hydrogen Peroxide Sterilizer

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

Legally Marketed Equivalent Device Name(s)
STERIZONE® VP4 Sterilizer (K141163)

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, single-channel flexible endoscopes, and rigid-channel devices including single-channel and double-channel rigid endoscopes.

The VP4 has been modified in order to make it compliant with the European Directive on the Restriction Of use of certain Hazardous Substances also known as « RoHS ». In addition, device software has been modified to include a maintenance mode, among other small changes. Finally, a new sensor has been adopted for monitor and control of chamber pressure.

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 seven 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 seven validation loads

Validation load #	Load description	Load weight[1] [1]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

Validation load #	Load description	Load weight[1] [1]Excluding the 25 lb loading rack
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 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. 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

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.

All RoHS-compliant components have undergone verification testing using the exact same test methods and acceptance criteria as used in the predicate device. The use of a new pressure transducer to monitor and control chamber pressure was verified using the same test methods and acceptance criteria as used in the predicate device.

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. 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 modified STERIZONE® VP4 Sterilizer is substantially equivalent to the predicate STERIZONE® VP4 Sterilizer (K141163). The design, materials, and functions of the sterilizers are identical. Changes to software and device components do not affect performance specifications or raise different questions regarding safety and effectiveness. A comparison between the two devices is provided in Table 2.

Table 2. Comparison Table between Modified and Predicate Devices.

	PREDICATE **STERIZONE VP4 K141163**	**Modified STERIZONE VP4**
Intended Use	Terminal sterilization of reusable medical devices in health care facilities	Same
General 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 healthcare	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

	PREDICATE **STERIZONE VP4 K141163**	**Modified STERIZONE VP4**
General Physical Process Parameters	Wall temperature, vaporization temperature, exposure times, flow rates, ozone concentration, component temperatures	Same
Chamber Volume	125L	Same
Software Control	PLC	Same

The predicate device has been modified by manufacturing all device components from RoHS compliant materials, upgrade of the software to include a maintenance mode among other functions, and use of a single pressure transducer to monitor and control chamber pressure. Verification testing has been completed on all modified components using the exact same methods and acceptance criteria as completed on the predicate device. Software verification and validation testing confirms that the modified device will perform as intended under the specified use conditions. Electrical safety, EMC and microbiology testing has been completed on the modified device confirming that it is both as safe and as effective as the predicate device.

Conclusion

The performance testing demonstrates that the STERIZONE® VP4 Sterilizer is substantially equivalent to the identified predicate devices.