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

December 17, 2014

TSO_3 Inc.
C/O Thomas Richards, Ph.D.
Consultant
IM3, Inc.
512F NE 81st Street, Suite110
Vancouver, WA 98665

Re: K141163
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: December 8, 2014
Received: December 10, 2014

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
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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)*
K141163

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

ANNEX 1

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)

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ANNEX 1

510(k) Summary

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Summary Date
December 12, 2014

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)
STERRAD® 100NX® Sterilizer with DUO Cycle (K111377)
Amsco® V-PRO® maX Low Temperature Sterilization System (K131120)

Process description

The STERIZONE® VP4 Sterilizer offers a single pre-set sterilization cycle designed for the sterilization of general instruments, single channel flexible endoscopes, rigid and semi-rigid channeled devices including single channel and double channel rigid endoscopes.

The STERIZONE® VP4 Sterilizer uses dual sterilants, vaporized hydrogen peroxide (H_2O_2) and ozone (O_3), in a multiphase process.

Upon loading the medical devices into the sterilization chamber and closure of the door, the chamber is subjected to a vacuum of 1 Torr (referred to as pre-conditioning step). The first cycle phase (Phase 1) is initiated with the Dynamic H_2O_2 exposure step. During this step, a 50 weight-percent hydrogen peroxide solution (referred to as 125-280 Solution™) is injected at a fixed injection rate in vapor form into the sterilization chamber through a continuous micro-pulsed injection until a differential pressure set point of 19 Torr is reached (i.e., the actual chamber pressure is 20 Torr, less the initial vacuum of 1 Torr, which is equivalent to a "differential pressure" or "ΔP" of 19 Torr). The total amount of hydrogen peroxide introduced into the sterilization chamber and thus the duration of the injection varies depending on load composition (e.g. surface area), weight and temperature.

The second step of the cycle phase is the H_2O_2 Reduction Step. During this step, a set concentration of ozone is injected into the chamber and reacts with residual hydrogen peroxide to form hydroxyl radicals.

During the second cycle phase (Phase 2), the same sequence is repeated, including the Dynamic H_2O_2 exposure and H_2O_2 reduction steps. The full Cycle is then completed with an evacuation and ventilation, through a catalytic converter, to the atmosphere, at which point the chamber door can be safely opened.

The cycle process parameters are summarized in Table 1.

Table 1. STERIZONE® VP4 Sterilizer – Cycle process parameters

Hydrogen peroxide exposure					Ozone exposure		Nb of phases
Hydrogen peroxide solution	Chamber differential pressure set point	Time	Sterilant injected	Vaporizer / Chamber temperature	O_3 injection	O_3 dwell	
125-280 Solution™ (H_2O_2 50 wt%)	19 Torr	210-600 sec*	8.4-24 g*	120°C / 41 ± 3°C	2 mg/L	5 min	2

* Vaporized hydrogen peroxide injection/exposure time (Dynamic H_2O_2 exposure step) varies with load composition and conditions. The quantity of vaporized hydrogen peroxide injected is directly related to the time required to reach a pressure differential of 19 Torr in the chamber, for load temperature ranging from 20°C to 26°C. If the H_2O_2 injection time is less than 210 seconds, or greater than 600 seconds, the cycle will abort.

Intended 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 dual sterilants 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 2. 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 2. Description of the seven validation loads

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

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

Description of Device

The STERIZONE® VP4 Sterilizer sterilization chamber has a capacity of 4.4 cu. ft. (125 liters). It requires oxygen (94% pure and greater), electricity and the 125-280 Solution™ containing 50% hydrogen peroxide by weight. Both hydrogen peroxide and ozone are used in a multiphase process.

The STERIZONE® VP4 Sterilizer is equipped with a factory-programmed control system offering a unique sterilization cycle.

Processed medical instruments are ready to use immediately after the cycle ends; no aeration is required.

Polypropylene non-woven wrapping material, non-woven polyethylene (Tyvek™) with polyester/LDPE transparent film pouches, and vaporized hydrogen peroxide compatible aluminium containers using disposable polypropylene filters, are used as packaging for medical devices to be sterilized. Plastic and metal trays are also suitable packaging means when combined with polypropylene wraps.

A self-contained biological indicator containing spores of *G. stearothermophilus*, incorporated into a test pack, is recommended to monitor cycle performance.

The STERIZONE® VP4 Sterilizer could be installed as a free standing unit or recessed behind the wall.

No exhaust gas ventilation duct is required as long as the room is adequately ventilated.

Effectiveness

The STERIZONE® VP4 Sterilizer performance validation testing was performed 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} at the complete cycle.

This process has been demonstrated to be effective for terminal sterilization of packaged reusable medical devices.

Safety

The 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 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: 2012
- International Electrotechnical Commission (IEC) Standard 61010-1 :2001, 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.

To ensure optimum performance, the user must ensure the materials, instruments and devices to be sterilized are thoroughly cleaned and dried, that the instrument manufacturer's instructions are followed, and that each sterilization load is monitored with biological and chemical sterilization process indicators.

The software controls of the STERIZONE® VP4 Sterilizer have been designed providing safeguards that only intended operating cycles function to completion. Process parameters falling outside acceptable range will cancel the cycle and provide appropriate information identifying the source of the problem detected.

The following Table 3 summarizes the safety and effectiveness testing performed for the STERIZONE® VP4 Sterilizer.

Table 3. Summary of Safety and Effectiveness testing performed for the STERIZONE® VP4 Sterilizer

	Performance Requirements for Effectiveness	*Results*
1	Effective to sterilize medical devices inoculated with 10^6 microorganism at the half-cycle conditions (Half-cycle validation testing)	Met requirements
2	Effective to sterilize medical devices inoculated with 10^6 microorganism in the presence of organic and inorganic matter at the complete cycle (Simulated-use testing)	Met requirements
3	Sterilize medical devices in real life conditions (In-use testing)	Met requirements
4	Pass the AOAC Sporicidal Screening Test	Met requirements
5	Sterilize effectively on non-woven polyethylene sterilization pouches, rigid aluminum containers and wrapped trays	Met requirements
6	Sterilization efficacy is repeatable	Met requirements
	Performance Requirements for Safety	
1	Sterilant is not toxic for users and patients	Met requirements
2	Most of the materials used in the manufacturing of medical devices are compatible with the hydrogen peroxide-ozone sterilization process	Met requirements
3	Sterilizer complies with electrical safety standards UL 61010-1, CAN/CSA 61010-1, EN/IEC 61010-1 and 61010-2-040	Met requirements
4	Sterilizer complies with EMI/EMC requirements of FCC 47CFR, part 18, subpart B, and IEC 613261	Met requirements
5	A Fault Tree Analysis and Mitigation (FTA-MIT) analysis have been preformed on the sterilizer and potential hazards were identified and mitigations were implemented among the control software safeties and design features	Met requirements
6	A Failure Mode Effects and Criticality Analysis (FMECA) was done for each component of the sterilizer and safeties were included in the design of the device according to the findings of this study (built-in safeties)	Met requirements
7	The amount of hydrogen peroxide and ozone remaining on containers and pouches immediately after cycle is not significant	Met requirements
8	There are no toxic residue or by-products residues remaining in/on medical product after the sterilization cycle is completed. After the cycle is completed, medical devices are cool to touch and ready to use immediately (no aeration is required)	Met requirements
9	The sterilization process is safe from an occupational safety point of view	Met requirements

Substantial equivalence

The STERIZONE® VP4 Sterilizer ("VP4") is substantially equivalent to the STERRAD® 100NX® Sterilizer with DUO Cycle (K111377) and STERIS (Amsco®) V-PRO® maX Low Temperature Sterilization System (K131120). Table 4 summarizes the general specifications, indications, and overall technological characteristics for both the VP4 and predicate devices.

Table 4. General comparison of technical specifications, technology, and indications for the subject device and predicate devices.

	Subject Device: STERIZONE® VP4 	*Predicate Device:* STERRAD 100NX K111377 	*Predicate Device:* STERIS V-PRO maX K131120 
Intended Use	Terminal sterilization of reusable medical devices in health care facilities	Same	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 health care facilities.	The STERRAD® 100NX® Sterilizer is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to safely sterilize medical instruments and materials without leaving toxic residue.	The Amsco V-PRO maX Low Temperature Sterilization System, with VAPROX® HC Steriant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and non-metal medical devices used in health care facilities.
Sterilant	Vaporized Hydrogen Peroxide / Ozone	Vaporized Hydrogen Peroxide	Vaporized Hydrogen Peroxide
H_2O_2 Concentration by Weight	50%	59-94% Depending on Cycle	59%
Post H_2O_2 injection step	Ozone injection / Dwell	Air pulse / Dwell / Plasma	Air pulse / Dwell
Number Pulses	2	2	4

	Subject Device: STERIZONE® VP4	*Predicate Device:* STERRAD 100NX K111377	*Predicate Device:* STERIS V-PRO maX K131120
			
Dimensions	H: 75.5 in (191.8 cm) W: 30.5 in (77.5 cm) D: 48.6 in (123.5 cm)	H: 70.5 in (179.1 cm) W: 30.5 in (77.5 cm) D: 40.0 in (102 cm)	H: 75.1 in (190.8 cm) W: 33.0 in (83.8 cm) D: 37.6 in (95.4 cm)
Weight	1,245 lb (565 kg)	938-1,006 lb (425-457 kg)	788-910 lb (357-413 kg)
Chamber Volume	125 L	152 L	136 L
Equipment Operating Temperature	20-26 °C Same as Load Temp	18-35 °C (64-95 °F)	5-40°C (41-104 °F)
Chamber (Wall) Temperature	41 °C	<55 °C	50 °C
Load Temperature	20-26 °C	Not Specified	Not Specified
H_2O_2 Vaporizer Temperature	120 °C (under vacuum)	75 °C (under vacuum)	60 °C (under vacuum)
Number of Pre-Programmed Cycles	1	4 • Standard • Flex Scope • Express • DUO	3 • Non Lumen • Lumen • Flexible
Key Critical Process Parameters	Differential Chamber Pressure (ΔP) & Load Temperature	H_2O_2 Dose & Exposure Time	H_2O_2 Dose & Exposure Time
Use of Pre-Conditioning Step	YES	YES	YES
Use of Secondary Step to Remove Residual H_2O_2 (technology)	YES (ozone, acts as a sterilant)	YES (plasma)	NO
Use of Aeration Step	YES	YES	YES

The performance characteristics and intended use of the STERIZONE® VP4 Sterilizer are the same as for the STERRAD® 100NX® Sterilizer (K111377) and the Amsco® V-PRO® maX Low Temperature Sterilization System (K131120) (Table 5).

Table 5. Comparison between the intended use and claims for the STERIZONE® VP4 Sterilizer, the STERRAD® 100NX® Sterilizer and the Amsco® V-PRO® Sterilizer

Feature	STERIZONE® VP4			STERRAD® 100NX® (K111377)			Amsco® V-PRO® maX (K131120)		
Intended use	Terminal sterilization of reusable medical devices in health care facilities			Terminal sterilization of reusable medical devices in health care facilities			Terminal sterilization of reusable medical devices in health care facilities		
Labeling/ Indications 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.			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.			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.		
Lumen claims*		I.D. (mm)	Lumen (mm)		I.D. (mm)	Lumen (mm)		I.D. (mm)	Lumen (mm)
	Rigid	≥ 0.7	≤ 500	Rigid	≥ 0.7	≤ 500	Single Rigid	≥ 0,77	≤ 500
	Double Rigid	≥ 0.7	≤ 500	-	-	-	Double rigid	≥0,77	≤500
	Flexible	≥ 1	≤ 850	Flexible	≥ 1	≤ 850	Flexible	≥ 1	≤ 1050
					≥ 1	≤ 875*			

*Lumen claims for the DUO Cycle of the STERRAD® 100NX Sterilizer.

Therefore, based on the foregoing information, the STERIZONE® VP4 Sterilizer is substantially equivalent to the STERRAD® 100NX® Sterilizer (K111377) and to the Amsco® V-PRO® maX Low Temperature Sterilization System (K131120) with respect to intended use, mode of action, performance and safety characteristics.

In particular, all three devices require only exposure to vaporized H_2O_2 to achieve a sterility assurance level (SAL) of 10^{-6}. However, only the STERIZONE® VP4 and the STERRAD® 100NX® Sterilizers incorporate a subsequent step intended to reduce residual hydrogen peroxide (ozone and plasma respectively). The STERIZONE® VP4 Sterilizer is a dual sterilization system that uses ozone which reacts with residual hydrogen peroxide to form hydroxyl radicals.

The differences between the subject device and predicates are not critical to the intended use of the device and do not raise new questions of safety and effectiveness when the device is used as labeled.

Conclusion

The STERIZONE® VP4 Sterilizer is as safe and as effective and is substantially equivalent to the identified predicates.