February 10, 2023

PRIMUS Sterilizer Company, LLC
% Ankur Naik
Managing Director
IZiel Healthcare
14, Hadapsar Industrial Estate, Hadapsar
Pune, Maharashtra 411013
India

Re: K221474
Trade/Device Name: PRIMUS Healthcare Sterilizer (Model PSS11-HC)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: January 12, 2023
Received: January 12, 2023

Dear Ankur Naik:

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,

Clarence W. Murray III -S

Clarence W. Murray, III, PhD
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221474

Device Name
PRIMUS Healthcare Sterilizer (Model PSS11-HC)

Indications for Use *(Describe)*
The PRIMUS Healthcare Sterilizer (Model PSS11-HC) is designed for use in surgery, central sterile, and surgery centers. The PRIMUS Healthcare Sterilizer provides efficient steam sterilization of non-porous and porous, heat and moisture stable materials. The sterilizer can be used on various materials that withstand operating temperatures; however, the materials that cannot withstand operating temperatures should not be sterilized using the PRIMUS Healthcare Sterilizer.

A table describing the Cycle, Exp. temp., Exp. time, Dry time, Recommended load, and maximum items per chamber size is available on the next page.

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."

Cycle	Factory Settings			Recommended Load (Note 1)	Total Load Weight	Maximum Items per Chamber Size
	Exp. Temp.	Exp. Time	Dry Time			HC
PREVAC 1 (vac)	270ºF (132ºC)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17
				Single Fabric Pack	0.2lb	1
PREVAC 2 (vac)	275ºF (135ºC)	3 min	30 min	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17
				Single Fabric Pack	0.2lb	1
Steam-Flush Pressure Pulse 1	270ºF (132ºC)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17
				Single Fabric Pack	0.2lb	1
Steam-Flush Pressure Pulse 2	275ºF (135ºC)	3 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17
				Single Fabric Pack	0.2lb	1
Immediate Use - PREVAC	270ºF (132ºC)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	25lb	1
Immediate Use - Gravity (Notes 1-3)	270ºF (132ºC)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	25lb	1

Cycle	Factory Settings			Recommended Load (Note 1)	Total Load Weight	Maximum Items per Chamber Size
	Exp. Temp.	Exp. Time	Dry Time			HC
Immediate Use - Gravity (Notes 1-3)	270ºF (132ºC)	10 min	1 min	Unwrapped porous or non-porous single instrument	25lb	1
				Unwrapped porous & non-porous instrument trays. up to 25 lb per tray	25lb	1
GRAVITY 1	250ºF (121ºC)	30 min	30 min	Double Wrapped instrument trays	225lb	9
				Fabric packs	3lb	17
GRAVITY 2	270ºF (132ºC)	15 min	30 min	Double Wrapped instrument trays	225lb	9
				Fabric packs	3lb	17
Bowie Dick Test (vac)	275ºF (132ºC)	3.5 min	3 min	Bowie-Dick Test Pack or equivalent (1) in an EMPTY chamber	-	1 Test Pack
Leak Test (Note 4)	N/A	N/A	N/A	Empty chamber	N/A	N/A

TABLE NOTES

1. Load configurations during testing validations follow ANSI/AAMI ST8:2013 standard for Hospital Steam Sterilizers where applicable. All fabric packs and instrument trays are constructed as described in ANSI/AAMI ST8. For guidance on loading the sterilizer, refer to ANSI/AAMI ST79:2017 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
2. At the end of an immediate use or express cycle items may NOT be dry.
3. The recommended exposure time and temperature for unwrapped, non-porous, immediate use cycle loads (e.g., metal instruments) is 3 minutes at 275°F (135°C).
4. Vacuum leak test parameters are not adjustable. The cycle run for leak test includes 15 minutes of dry cycle, 5 min for equalization within the chamber and 15 mins for the leak test run.

510(k) SUMMARY – K221474

510(k) summary for PRIMUS Healthcare Sterilizer is provided in accordance with 21 CFR 807.92.

Date:	10 February, 2023
Submitter (Owner):	Patrick Hansen, PE VP Engineering PRIMUS Sterilizer Company, LLC 9736 Forest City Road Suite 100 Orlando, fl 32810 Telephone No.: +1-402-3444200-1214 Fax No.: +1-402-344-4242 Email: phansen@spire-is.com
510(k) Contact Person:	Ankur Naik Managing Director IZiel Healthcare 14, Hadapsar Industrial Estate Hadapsar, Pune – 411013, India. P: +91 72762 12555 M: +91 7069553814 Email: ankur.naik@izielhealthcare.com
Device Trade Name:	PRIMUS Healthcare Sterilizer (Model PSS11-HC)
Regulation Number:	880.6880
Regulation Description:	A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam.
Review Panel:	General Hospital
Device Class:	Class II
Product Code:	FLE
Predicate Device:	1. PRIMUS PSS8 Steam Sterilizer Series (K093333) **Regulation number**: 21 CFR 880.6880 **Regulation Name:** Steam Sterilization **Regulatory Class**: II **Product Code:** FLE **Review panel:** General Hospital 2. AMSCO CHIMERON Small Steam Sterilizer (K111223) **Regulation number**: 21 CFR 880.6880 **Regulation Name:** Steam Sterilization **Regulatory Class:** II **Product Code:** FLE **Review panel:** General Hospital

Device Description:

PRIMUS Healthcare Sterilizers are compliant with AAMI ST8:2013 and manufactured in compliance with ISO 13485:2016 and FDA's Good Manufacturing Practice (GMP) for Medical Devices. Each sterilizer is equipped with a height-adjustable, steel floor stand. On freestanding units, stainless steel cabinet side panels enclose the sterilizer body and piping. A Back Cabinet Panel is provided as an optional feature on single door, freestanding units where the unit is accessible on all sides.

The PRIMUS Healthcare Series Steam Sterilizer consists of the following components and accessories:

1. **Jacket Assembly (sterilizer vessel)**

   A Type 316L stainless steel chamber and a Type 304 stainless steel jacket are welded together to form the sterilizer vessel. The sterilizer vessel is ASME rated at 45 psig (3.06 Bar) and insulated. Steam-supply opening inside the chamber is shielded by a Type 316L stainless steel baffle. The unique design of the chamber jacket allows for an even distribution of heat and prevents the formation of condensation on the chamber walls.

2. **Chamber Finish**

   The sterilizer features a 316L SS (stainless steel) brilliant PRI-Mirror chamber finish found in all PRIMUS models achieving a 10 Ra (0.026 microns) measurement.

   The chamber has a full-length steam baffle and two drains positioned in the chamber to maximize steam distribution and cross-flow within the chamber.

3. **Chamber Door**

   Door is constructed of a single formed piece of Type 316L stainless steel. The door is insulated to reduce the surface temperature of the stainless-steel door cover.

   Sterilizers have either single or double doors. They are equipped with manual or hydraulically powered vertical sliding door(s). All doors are sealed with a continuous silicone O-Ring gasket, recessed within the chamber head ring.

4. **Insulation**

   Superior heat loss reduction is achieved with one-inch fiberglass insulation overlaid with 0.05-inch aluminum sheet metal.

5. **Chamber Drain System**

   Drain system is designed to prevent pollutants from entering into the water-supply system and sterilizer

6. **Drain Water Quench (Piping System)**

   The piping system provides automatic condensing of chamber steam and discharges to the floor drain. Cooling water is added to ensure discharge temperature is below 60°C (140°F). A separate temperature switch is included to regulate the volume of water so as not to exceed the required amount necessary to achieve the target temperature. The steam piping is constructed of stainless steel (standard) or brass and copper (optional) and includes a steam strainer and brass pressure regulator.

7. **Vacuum system**

   Chamber pressure is reduced during the conditioning phase and drying phase through the means of either a standard water ejector or a liquid ring vacuum pump. Following the drying phase, the chamber is returned to atmospheric pressure by admitting air through a 0.3-micron bacteria-retentive filter.

8. **Steam Source**

   Sterilizers are piped, valved, and trapped to receive building-supplied steam delivered at 50 to 80 psig (344.7 to 551.6 kPa) dynamic. If a building steam source is not available, an electric carbon-steel steam generator or electric stainless steel steam generator may be provided to supply steam to the sterilizer.

9. **Control system:**

   The PRIMUS Healthcare Sterilizer consists of a PLC control system with standard eleven pre-programmed, validated cycles to meet specific processing requirements. User access, profiles, simplified screens, cycle names, and additional options can be configured or toggled on/off easily in the user-friendly menus. All control configurations are performed through the touch screen display. Four levels of authorization come standard with increasing varying access permissions. Standard levels include default, operator, technician, and administrator. Additional levels can be custom configured.

   The operator has an interface with a touch screen and thermal printer which is located on the load or nonsterile end of the sterilizer. The thermal Printer located below the touch screen, provides an easy-to-read printed record of all pertinent cycle data on 2-1/4” wide paper. Data is automatically printed at the beginning and end of each cycle and at transition points during the cycle. A duplicate print can be obtained of the last cycle run.

Device Configurations:

Table 1 below lists the details of PRIMUS Healthcare Sterilizer with validated load capacity in compliance with AAMI ST8 guidelines.

Table 1: Available Sterilizer configurations

Configuration (W x H x L)	Chamber Capacity	Model #
PRIMUS Steam Sterilizer, 26”x30”x41”	18.51 ft3 / 626 L	PSS11-HC

Intended use / Indications for Use:

The PRIMUS Healthcare Sterilizer model PSS11-HC is designed for use in surgery, central sterile, and surgery centers. The PRIMUS Healthcare Sterilizer provides efficient steam sterilization of non-porous and porous, heat and moisture stable materials. The sterilizer can be used on various materials that withstand operating temperatures; however, the materials that cannot withstand operating temperatures should not be sterilized using the PRIMUS Healthcare Sterilizer.

Factory Programmed Sterilization Cycles

The PRIMUS Healthcare Sterilizers are validated on standard cycles as per AAMI standard ST8:2013.

Table 2: Factory Programmed Sterilization Cycles for PRIMUS Healthcare Sterilizer

Cycle	Factory Settings			Recommended Load (Note 1)	Total Load weight	Maximum Items per Chamber Size
	Exp. Temp.	Exp. Time	Dry Time			HC
PREVAC 1 (vac)	270ºF (132ºC)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17
				Single Fabric Pack	0.2lb	1
PREVAC 2 (vac)	275ºF (135ºC)	3 min	30 min	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17

Cycle	Factory Settings			Recommended Load (Note 1)	Total Load weight	Maximum Items per Chamber Size
	Exp. Temp.	Exp. Time	Dry Time			HC
				Single Fabric Pack	0.2lb	1
Steam-Flush Pressure Pulse 1	270ºF (132ºC)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17
				Single Fabric Pack	0.2lb	1
Steam-Flush Pressure Pulse 2	275ºF (135ºC)	3 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	225lb	9
				Fabric packs	3lb	17
				Single Fabric Pack	0.2lb	1
Immediate Use - PREVAC	270ºF (132ºC)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	25lb	1
Immediate Use - Gravity (Notes 1-3)	270ºF (132ºC)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	25lb	1

Cycle	Factory Settings			Recommended Load (Note 1)	Total Load weight	Maximum Items per Chamber Size
	Exp. Temp.	Exp. Time	Dry Time			HC
Immediate Use - Gravity (Notes 1-3)	270ºF (132ºC)	10 min	1 min	Unwrapped porous or non-porous single instrument	25lb	1
				Unwrapped porous & non-porous instrument trays. up to 25 lb per tray	25lb	1
GRAVITY 1	250ºF (121ºC)	30 min	30 min	Double Wrapped instrument trays	225lb	9
				Fabric packs	3lb	17
GRAVITY 2	270ºF (132ºC)	15 min	30 min	Double Wrapped instrument trays	225lb	9
				Fabric packs	3lb	17
Bowie Dick Test (vac)	275ºF (132ºC)	3.5 min	3 min	Bowie-Dick Test Pack or equivalent (1) in an EMPTY chamber		1 Test Pack
Leak Test (Note 4)	N/A	N/A	N/A	Empty chamber		N/A

TABLE NOTES

1. Load configurations during testing validations follow ANSI/AAMI ST8:2013 standard for Hospital Steam Sterilizers where applicable. All fabric packs and instrument trays are constructed as described in ANSI/AAMI ST8. For guidance on loading the sterilizer, refer to ANSI/AAMI ST79:2017 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.
2. At the end of an immediate use or express cycle items may NOT be dry.
3. The recommended exposure time and temperature for unwrapped, non-porous, immediate use cycle loads (e.g., metal instruments) is 3 minutes at 275℉ (135℃).
4. Vacuum leak test parameters are not adjustable. The cycle run for leak test includes 15 minutes of dry cycle, 5 min for equalization within the chamber and 15 mins for the leak test run.

Comparison to Predicate Devices

Two predicate devices are selected in this submission for the PRIMUS Healthcare Sterilizer.

Predicate device 1: PRIMUS PSS8 Steam Sterilizer Series (K093333)

Predicate device 2: Amsco Chimeron Small Steam Sterilizer (K111223)

The details of the comparison between the subject device and predicate devices are provided below:

Table 3: Technological Characteristics Comparison Table between the Subject Device and Predicate Device

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
Product Name	PRIMUS Healthcare Sterilizer	PRIMUS Steam Sterilizers	Amsco Chimeron Small Steam Sterilizer	Not Applicable
Manufacturer	PRIMUS Sterilizer Company, LLC	PRIMUS Sterilizer Company, LLC	Steris Healthcare	Not Applicable
Regulation Number	880.6880	880.6880	880.6880	Identical
Product Code	FLE	FLE	FLE	Identical
Product Class	II	II	II	Identical
Intended Use / Indications for Use	The PRIMUS Healthcare Sterilizer model HC is designed for use in surgery, central sterile, and surgery centers. The PRIMUS Healthcare Sterilizer provides efficient steam sterilization of non-porous and porous, heat and moisture stable materials. The sterilizer can be used on various materials that withstand operating temperatures; however, the	The PRIMUS PSS8 Steam Sterilizer Series are designed for use in the hospital operating suites, central sterile supply and clinical laboratories. The PRIMUS PSS8 Steam Sterilizer Series provide efficient steam sterilization of non-porous and porous, heat and moisture stable materials.	Amsco Chimeron Small Steam Sterilizer models 16, 16C, 16CS, 16S, 20, 20C, 20CS and 20S are designed for sterilization of heat and moisture-stable materials in healthcare facilities.	Identical

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
	materials that cannot withstand operating temperatures should not be sterilized using the PRIMUS Healthcare Sterilizer.			
Operating Principle	Steam is the sterilizing agent.	Steam is the sterilizing agent.	Steam is the sterilizing agent.	Identical
Sterilization Cycles Offered	Model is offered with: Prevac, Gravity, SFPP, Leak test	All models are offered with: Vacuum, Gravity, Liquids, Test (Vac)	Prevac, Gravity, SFPP (Models 16CS, 16S, 20CS & 20S only), Liquids, Leak test.	Identical
Sterilization Cycle Parameters	Prevac (VAC) cycle: • Prevac 1 - Exposure for 4 minutes at 132ºC • Prevac 2 - Exposure for 3 minutes at 135ºC	Prevac (VAC) cycle: • Exposure for 4 minutes at 132ºC	Prevac (VAC) cycle: • Exposure for 4 minutes at 132ºC • Exposure for 3 minutes at 135ºC	The Prevac 1 cycle is identical. The Prevac 2 cycle is identical to predicate 2.
	Immediate Use (Prevac): • Exposure for 4 minutes at 132ºC	Not available	Immediate Use (Prevac): • Exposure for 4 minutes at 132ºC	Identical to predicate 2

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
	Immediate Use – Gravity: • Exposure for 4 minutes at 132ºC • Exposure for 10 minutes at 132ºC	Not available	Immediate Use – Gravity: • Exposure for 3 minutes at 132ºC • Exposure for 10 minutes at 132ºC	Similar to predicate 2. The difference in exposure times is minimal and the cycle itself has been validated.
	Gravity: • Gravity 1 – Exposure for 30 minutes at 121ºC • Gravity 2 - Exposure for 15 minutes at 132ºC	Gravity: • Exposure for 30 minutes at 121.1ºC	Gravity: • Exposure for 30 minutes at 121ºC • Exposure for 15 minutes at 132ºC • Exposure for 25 minutes at 132ºC	Gravity 1 cycle is identical. Gravity 2 cycle is identical with predicate 2.
	Steam-Flush Pressure Pulse (SFPP): • SFPP 1 - Exposure for 4 minutes at 132ºC • SFPP 2 - Exposure for 3 minutes at 135ºC	Not Available	Steam-Flush Pressure Pulse (SFPP): • Exposure for 4 minutes at 132ºC • Exposure for 3 minutes at 135ºC	Identical to predicate 2.
	Bowie Dick Test (DART): • Exposure for 3.5 minutes at 132ºC	Bowie Dick Test (DART): • Exposure for 3.5 minutes at 132ºC	Bowie Dick Test (DART): • Exposure for 3.5 minutes at 132ºC	Identical

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	10^{-6}	Identical
Chamber Sizes	26” x 30” x 41”	Multi-functional Sterilizer 16” x 16” x 26” (Model PSS8-AA-M) 20” x 20” x 38” (Model PSS8-A-M) 26” x 26” x 39” (Model PSS8-B-M) 26” x 26” x 49” (Model PSS8-C-M) 26” x 26” x 67” (Model PSS8-D-M) 26” x 36” x 39” (Model PSS8-E-M) 26” x 36” x 48” (Model PSS8-F-M) 26” x 36” x 60” (Model PSS8-G-M) 32” x 36” x 48” (Model PSS8-G.1-M) 26” x 63” x 48” (Model PSS8-J-M) 26” x 63” x 76” (Model PSS8-K-M)	16” x 16” x 26” (Models 16, 16C, 16CS and 16S) 20” x 20” x 38” (Models 20, 20C, 20CS and 20S)	Similar to model PSS8-F-M of predicate device 1. The volume of chamber for model HC is low as compared to model PSS8-F-M of predicate device 1.

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
		35” x 57” x 60” (Model PSS8-M-M)		
Chamber Door	Type 316L Stainless-steel Vertical Sliding	Type 316L Stainless-steel Vertical & Horizontal Sliding	Type 316L Stainless-steel Vertical Sliding (26” x 26”)	Identical
Instrument tray load	25 lbs each tray	12 lbs each tray	25 lbs each tray	Identical to predicate 2
Fabric pack	25 lbs	12 lbs	25 lbs	Identical to predicate 2
Control Technology	PLC Controller (Idec FC6A Micro system & Allen Bradley CompactLogix system), Touch Screen, 800 x 600 Pixel Display, Ink on Paper Impact Printer, Ethernet printing & PRI-SND	PLC Controller (PSS8 Trinity control) – door closed screen, Touch screen	Embedded controller, Touch Screen, 320 x 240 Pixel Display, Ink on Paper Printer	Similar. The proposed device has advanced control, display and printing features compared to predicate device which provides easy-to-read printed records and delivers realistic images and the brightest displays. The firmware has been validated.

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
Printer technology	Thermal printer (Ink-on-paper impact printer)	Thermal printer (dot-matrix technology and 32 characters per line printing)	Thermal printer (Ink-on-paper impact printer)	Identical to predicate 2.
Factory Programmed Sterilization Cycles	11 pre-programmed cycles.	6 pre-programmed cycles	Unknown	Similar The subject device uses PSS11 controller that allows for more pre-programmed cycles which help to meet specific processing requirements.
Safety Devices	Emergency Stop Button Pressure Relief Valve Door and Gasket Safety Switch Door interlocks (double door units only)	Pressure Relief Valve Door and Gasket Pressure Switches Door interlock	Pressure Relief Valve Chamber Float Switch Emergency Stop Switch	Identical
Built according to Standard	ANSI/AAMI ST8:2013 Hospital Steam	ANSI/AAMI ST8:2013 Hospital Steam	ANSI/AAMI ST8:2013 Hospital Steam	Identical

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
	Sterilizers	Sterilizers	Sterilizers	
Electrical Safety Standard	UL 61010-1:2012 (Ed.3+R:29 April 2016), UL 61010-2-040:2016 (Ed.2), (R2017) CSA C22.2#61010-1-12:2012 Ed.3+U1;U2, CSA C22.2#61010-2-040:2016 Ed.2	AAMI / ANSI / IEC 60601-1-2 (Second Edition 2001), UL 61010A-1, IEC 61010-1 Amendment 2, IEC 61010-2-041, UL 61010A-2-041, CAN/CSA-C22.2 No. 1010.2-041-96.	ANSI / UL 61010-1 (Ed.2), CAN/CSA C22.2 No. 61010-1 (Ed.2), UL 61010A-2-041 (Ed.1), CAN/CSA C22.2 No. 1010.2.041 (R2004)	Similar
Safety Valves	ASME Approved	ASME Approved	Unknown	Identical
Pressure Vessels	ASME Certified	ASME Certified	ASME Certified	Identical
Power boilers	ASME Code, Section I, Part PMB	Unknown	ASME Code, Section I, Part PMB	Identical
Chamber pressure	45 psig	45 psig	50 psig	Identical to predicate 1
Air filter	0.3 micron (optional 0.2 micron)	0.3 micron	Unknown	Identical
Electrical supply	Volts: 110 Phase: Single Amps: 10	Volts: 110 Phase: Single Amps: 10	Volts: 120 Phase: Single Amps: 2.0	Identical to predicate 1
Steam Source pressure	50 to 80 psig Dynamic	50 to 80 psig Dynamic	50 to 80 psig Dynamic	Identical
Water Pressure	50 to 70 psig Dynamic	50 to 70 psig Dynamic	30 to 50 psig Dynamic	Identical to predicate 1
Air Pressure	60 to 80 psi Dynamic	60 to 80 psi Dynamic	Unknown	Identical
Piping construction material	Brass	Brass	Brass	Identical

Comparable Properties	Subject Device	Predicate Device 1 (K093333)	Predicate Device 2 (K111223)	Comparison Results
Fitting material	Copper	Copper	Unknown	Identical

Performance Data

PRIMUS Healthcare Sterilizer complies with the requirements of FDA **Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities** and the subject device performance test demonstrates that it meets the acceptance criteria of the test methods described below:

Name of Test Methodology	Purpose	Acceptance Criteria	Results
Electrical Safety	To ensure that the device and its components meet the electrical safety requirements	Compliance to meeting standard specification UL 61010-1:2012 Ed.3+R:29 Apr 2016 and UL 61010-2-040:2016	Pass
EMC	To verify that the device meets EMC requirements	Compliance with IEC 60601-1-2 ed 4.0 (2014-02)	Pass
Low-voltage switchgear and control gear assemblies	To verify that theLow-voltage switchgear and control gear assemblies meets the standard requirement.	Compliance with IEC 61439-2 Low-voltage switchgear and control gear assemblies - Part 2: Power switchgear and control gear assemblies	Pass
Pressure Vessel Testing	To verify that the pressure vessel used for the Steam sterilizer meets the requirements for pressure vessel and is safe for use.	Compliance with standard ASME Boiler and pressure vessel code, Section VIII division 1	Pass

Name of Test Methodology	Purpose	Acceptance Criteria	Results
Control panel	To verify the control panel meets the requirement of UL 508A:2013	Compliance with standard Industrial Control Panels UL 508A:2013	Pass
Performance testing	To verify that all the cycles in the PRIMUS healthcare steam sterilizer meets the performance criteria defined in ANSI/AAMI/ST8.	Compliance to performance requirements defined in ANSI/AAMI/ST8:2013 (R2018)	Pass

The risks identified during risk analysis were reduced by applying suitable risk control measures and it was noted that there were no unacceptable risks after risk control measures.

Design verification and validation activities have been carried out both in-house and by outsourcing to appropriate third-party vendors. The design verification, design validation, and performance testing activities have been documented.

The PRIMUS Healthcare Sterilizers comply with the following standards:

- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI AAMI ST8:2013/(R)2018 - Hospital Steam Sterilizers
- ANSI AAMI IEC 62304:2006/A1:2016 - Medical device software - Software life cycle processes [Including Amendment 1 (2016)]
- ASME Section VIII: BPVC Section VIII-Rules for Construction of Pressure Vessels Division 1
- UL 61010-2-040 Ed. 2-2016 - Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use - Part 2-040: Particular

Requirements For Sterilizers And Washer-Disinfectors Used To Treat Medical Materials

- UL 61010-1 UL Standard for Safety Electrical Equipment For Measurement, Control, and Laboratory Use; Part 1: General Requirements
- NFPA 70, National Electrical Code (NEC) is the benchmark for safe electrical design, installation, and inspection to protect people and property from electrical hazards.
- CSA C22.2 NO. 61010-2-040:21 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (Adopted IEC 61010-2-040:2020, third edition, 2020-05, with Canadian deviations)
- Guidance on Premarket Notification 510(k) for Sterilizers Intended for Use in Health Care Facilities
- IEC 61439-2:2020 Low-voltage switchgear and control gear assemblies - Part 2: Power switchgear and control gear assemblies
- ISO 14971:2012 Medical devices - Application of risk management to medical devices
- EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices.
- ISO 15223-1 Third Edition 2016-11-01 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.
- UL 508A, Edition 3 Industrial Control Panels

Summary of Clinical Testing

Clinical studies are not required.

Conclusion

The conclusion drawn from the nonclinical tests that demonstrate that the device is as safe as effective and performs as well as better than legally marketed device.