



December 19, 2023

PRIMUS Sterilizer Company, LLC
% Ankur Naik
Managing Director
IZiel Healthcare
Pentagon P1, Office No. 601 and 604,
Magarpatta City, Hadapsar, Pune 411028,
Maharashtra India

Re: K233132

Trade/Device Name: PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: September 26, 2023
Received: September 27, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher K. Dugard
-S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control

and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233132

Device Name

PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB)

Indications for Use (Describe)

The PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB) 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.

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Table 1: Factory Programmed Sterilization Cycles for PRIMUS Healthcare Sterilizer Model PSS11-HA and PSS11-HB.

Cycle	Factory Settings			Recommended Load (Note 1)	PSS11-HA		PSS11-HB	
	Exp. Temp.	Exp. Time	Dry Time		Total Load Weight	Maximum Items per Chamber Size	Total Load Weight	Maximum Items per Chamber Size
PREVAC 1 (vac)	270°F (132°C)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4lb	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
PREVAC 2 (vac)	275°F (135°C)	3 min	30 min	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4lb	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
Steam-Flush Pressure Pulse 1	270°F (132°C)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4b	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
Steam-Flush Pressure Pulse 2	275°F (135°C)	3 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4lb	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
Immediate Use - PREVAC	270°F (132°C)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1	25lb	1

Cycle	Factory Settings			Recommended Load (Note 1)	PSS11-HA		PSS11-HB	
	Exp. Temp.	Exp. Time	Dry Time		Total Load Weight	Maximum Items per Chamber Size	Total Load Weight	Maximum Items per Chamber Size
				Unwrapped non-porous instrument trays, up to 25 lb per tray	75lb	3	200lb	8
Immediate Use - Gravity (Notes 1-3)	270°F (132°C)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	75lb	3	200lb	8
Immediate Use - Gravity (Notes 1-3)	270°F (132°C)	10 min	1 min	Unwrapped porous or non-porous single instrument	25lb	1	25lb	1
				Unwrapped porous & non-porous instrument trays. up to 25 lb per tray	75lb	3	200lb	8
GRAVITY 1	250°F (121°C)	30 min	30 min	Unwrapped non-porous single instrument	25lb	1	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	75lb	3	200lb	8
GRAVITY 2	270°F (132°C)	15 min	30 min	Unwrapped non-porous single instrument	25lb	1	25lb	1

Cycle	Factory Settings			Recommended Load (Note 1)	PSS11-HA		PSS11-HB	
	Exp. Temp.	Exp. Time	Dry Time		Total Load Weight	Maximum Items per Chamber Size	Total Load Weight	Maximum Items per Chamber Size
				Unwrapped non-porous instrument trays, up to 25 lb per tray	75lb	3	200lb	8
Bowie Dick Test (vac)	275°F (132°C)	3.5 min	3 min	Bowie-Dick Test Pack or equivalent (1) in an EMPTY chamber	-	1 Test Pack	-	1 Test Pack
Leak Test (Note 4)	N/A	N/A	N/A	Empty chamber	N/A	N/A	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 - K233132

510(k) summary of safety and effectiveness for PRIMUS Healthcare Sterilizer models PSS11HA and PSS11-HB are provided in accordance with 21 CFR 807.92.

Date:	18 December 2023
Submitter (Owner):	Patrick Hansen, PE VP Engineering PRIMUS Sterilizer Company, LLC 7936 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 Pentagon P1, Office No. 601 and 604, Magarpatta City, Hadapsar, Pune 411028, Maharashtra, India. P: +91 72762 12555 M: +91 7069553814 Email: ankur.naik@izielhealthcare.com
Device Trade Name:	PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB)
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 Healthcare Sterilizer (Model PSS11-HC) (K221474) Regulation number: 21 CFR 880.6880 Regulation Name: Steam Sterilization Regulatory Class: II Product Code: FLE Review panel: General Hospital

Device Description:

The PRIMUS Healthcare Sterilizer model PSS11-HA & PSS11-HB are designed for use in surgery, central sterile, and surgery centers. The PRIMUS Healthcare Sterilizer models PSS11-HA and PSS11-HB are used with eleven standard pre-programmed cycles (factory preset), which are listed in **Table 2** All cycles in the PSS11-HA and

PSS11-HB are validated and compliant with AAMI ST8:2013/(R) 2018. The unit is manufactured in compliance with ISO 13485:2016 and the FDA's Good Manufacturing Practice (GMP) for Medical Devices. The sterilizer unit 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 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:

PRIMUS Healthcare Sterilizer model PSS11-HA and PSS11-HB can use either the IDEC FC6A Microsystem or the Allen Bradley CompactLogix system platforms, depending on availability. The PSS11-H PRIMATIC 100 control software remains the same, and all functional and software specifications remain consistent between the platforms. The programmable logic controller (PLC) provides process control, while the human-machine interface (HMI) serves as the interface between the operator and the PLC.

The PRIMUS Healthcare Sterilizer models PSS11-HA and PSS11-HB 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:

Below, **Table 1** lists the details of the PSS11-HA and PSS11-HB models of the PRIMUS Healthcare Steam Sterilizer, along with their validated load capacity in accordance with the AAMI ST8 guidelines.

Table 1: Available Sterilizer configurations

Configuration (W x H x L)	Chamber Capacity	Model #
PRIMUS Steam Sterilizer, 20" x 20" x 38"	8.8 ft ³ / 249 L	PSS11-HA
PRIMUS Steam Sterilizer, 26" x 30" x 29"	13.09 ft ³ / 371 L	PSS11-HB

Intended use / Indications for Use:

The PRIMUS Healthcare Sterilizer (Models PS11-HA and PSS11-HB) 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 Model PSS11-HA and PSS11-HB.

Cycle	Factory Settings			Recommended Load (Note 1)	PSS11-HA		PSS11-HB	
	Exp. Temp.	Exp. Time	Dry Time		Total Load Weight	Maximum Items per Chamber Size	Total Load Weight	Maximum Items per Chamber Size
PREVAC 1 (vac)	270°F (132°C)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4lb	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
PREVAC 2 (vac)	275°F (135°C)	3 min	30 min	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4lb	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
Steam-Flush Pressure Pulse 1	270°F (132°C)	4 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4b	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
Steam-Flush Pressure Pulse 2	275°F (135°C)	3 min	30 mins	Double-wrapped instrument trays, up to 25 lb per tray	75lb	3	200lb	8
				Fabric packs	1.2lb	6	2.4lb	12
				Single Fabric Pack	0.2lb	1	0.2lb	1
Immediate Use - PREVAC	270°F (132°C)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1	25lb	1
				Unwrapped non-porous instrument	75lb	3	200lb	8

Cycle	Factory Settings			Recommended Load (Note 1)	PSS11-HA		PSS11-HB	
	Exp. Temp.	Exp. Time	Dry Time		Total Load Weight	Maximum Items per Chamber Size	Total Load Weight	Maximum Items per Chamber Size
				trays, up to 25 lb per tray				
Immediate Use - Gravity (Notes 1-3)	270°F (132°C)	4 min	1 min	Unwrapped non-porous single instrument	25lb	1	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	75lb	3	200lb	8
Immediate Use - Gravity (Notes 1-3)	270°F (132°C)	10 min	1 min	Unwrapped porous or non-porous single instrument	25lb	1	25lb	1
				Unwrapped porous & non-porous instrument trays. up to 25 lb per tray	75lb	3	200lb	8
GRAVITY 1	250°F (121°C)	30 min	30 min	Unwrapped non-porous single instrument	25lb	1	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	75lb	3	200lb	8
GRAVITY 2	270°F (132°C)	15 min	30 min	Unwrapped non-porous single instrument	25lb	1	25lb	1
				Unwrapped non-porous instrument trays, up to 25 lb per tray	75lb	3	200lb	8

Cycle	Factory Settings			Recommended Load (Note 1)	PSS11-HA		PSS11-HB	
	Exp. Temp.	Exp. Time	Dry Time		Total Load Weight	Maximum Items per Chamber Size	Total Load Weight	Maximum Items per Chamber Size
Bowie Dick Test (vac)	275°F (132°C)	3.5 min	3 min	Bowie-Dick Test Pack or equivalent (1) in an EMPTY chamber	-	1 Test Pack	-	1 Test Pack
Leak Test (Note 4)	N/A	N/A	N/A	Empty chamber	N/A	N/A	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.

Technological Characteristics Comparison

PRIMUS Healthcare Sterilizer (Model PSS11-HC), previously cleared under K221474, has been selected as the predicate device for this submission for the PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB).

The detailed comparison between the subject device and the predicate device is provided in the table below:

Table 3: Technological Characteristics Comparison

Comparable Properties	Subject Device	Predicate Device (K221474)	Comparison Results
Product Name	PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB)	PRIMUS Healthcare Sterilizer (Model PSS11-HC)	Not Applicable
Manufacturer	PRIMUS Sterilizer Company, LLC	PRIMUS Sterilizer Company, LLC	Not Applicable
Regulation Number	880.6880	880.6880	Identical
Product Code	FLE	FLE	Identical
Product Class	II	II	Identical
Intended Use / Indications for Use	The PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB) 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	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	Identical

Comparable Properties	Subject Device	Predicate Device (K221474)	Comparison Results
	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	materials that withstand operating temperatures; however, the 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.	Identical
Sterilization Cycles Offered	All models are offered with: Prevac, Gravity, SFPP, Immediate Use, Leak test	All models are offered with: Prevac, Gravity, SFPP, Immediate Use, Leak test	Identical
Sterilization Cycle Parameters	Prevac (VAC) cycle: • Prevac 1 -Exposure for 4 minutes at 132°C • Prevac 2 -Exposure for 3 minutes at 135°C	Prevac (VAC) cycle: • Prevac 1 -Exposure for 4 minutes at 132°C • Prevac 2 -Exposure for 3 minutes at 135°C	Identical
	Immediate Use (Prevac): • Exposure for 4 minutes at 132°C	Immediate Use (Prevac): • Exposure for 4 minutes at 132°C	Identical

Comparable Properties	Subject Device	Predicate Device (K221474)	Comparison Results
	Immediate Use – Gravity: - Exposure for 4 minutes at 132°C - Exposure for 10 minutes at 132°C	Immediate Use – Gravity: - Exposure for 4 minutes at 132°C - Exposure for 10 minutes at 132°C	Identical
	Gravity: - Gravity 1 – Exposure for 30 minutes at 121°C - Gravity 2 - Exposure for 15 minutes at 132°C	Gravity: - Gravity 1 – Exposure for 30 minutes at 121°C - Gravity 2 - Exposure for 15 minutes at 132°C	Identical
	Steam-Flush Pressure Pulse (SFPP): - SFPP 1 - Exposure for 4 minutes at 132°C - SFPP 2 - Exposure for 3 minutes at 135°C	Steam-Flush Pressure Pulse (SFPP): - SFPP 1 - Exposure for 4 minutes at 132°C - SFPP 2 - Exposure for 3 minutes at 135°C	Identical
	Bowie Dick Test (DART): Exposure for 3.5 minutes at 132°C	Bowie Dick Test (DART): Exposure for 3.5 minutes at 132°C	Identical
Sterility Assurance Level (SAL)	10 ⁻⁶	10 ⁻⁶	Identical
Chamber Sizes	PSS11-HA: 20" x 20" x 38" PSS11-HB: 26" x 30" x 29"	26" x 30" x 41"	The volume of the chamber for the subject devices are lower when compared to the volume of the Predicate device.

Comparable Properties	Subject Device	Predicate Device (K221474)	Comparison Results
			However, the subject devices are validated with ST8, and the device passed the test. Hence, this does not raise any concerns related to the safety and efficacy of the device.
Chamber Door	Type 316L Stainless-steel Vertical Sliding	Type 316L Stainless-steel Vertical Sliding	Identical
Instrument tray load	25 lbs each tray	25 lbs each tray	Identical
Fabric pack	25 lbs	25 lbs	Identical
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 (Idec FC6A Micro system & Allen Bradley CompactLogix system), Touch Screen, 800 x 600 Pixel Display, Ink on Paper Impact Printer, Ethernet printing & PRI-SND	Identical
Printer technology	Thermal printer (Ink-on-paper impact printer)	Thermal printer (Ink-on-paper impact printer)	Identical
Factory Programmed Sterilization Cycles	11 pre-programmed cycles	11 pre-programmed cycles	Identical.
Safety Devices	Emergency Stop Button	Emergency Stop Button	Identical

Comparable Properties	Subject Device	Predicate Device (K221474)	Comparison Results
	- Pressure Relief Valve - Door and Gasket Safety Switch - Door interlocks (double door units only)	- Pressure Relief Valve - Door and Gasket Safety Switch - Door interlocks (double door units only)	
Built according to Standard	ANSI/AAMI ST8:2013/(R) 2018 Hospital Steam Sterilizers	ANSI/AAMI ST8:2013/(R) 2018 Hospital Steam Sterilizers	Identical
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	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	Identical
Safety Valves	ASME Approved	ASME Approved	Identical
Pressure Vessels	ASME Certified	ASME Certified	Identical
Power boilers	ASME Code, Section I, Part PMB	ASME Code, Section I, Part PMB	Identical
Chamber pressure	45 psig	45 psig	Identical
Air filter	0.3 micron (optional 0.2 micron)	0.3 micron (optional 0.2 micron)	Identical
Electrical supply	Volts: 110 Phase: Single Amps: 10	Volts: 110 Phase: Single Amps: 10	Identical

Comparable Properties	Subject Device	Predicate Device (K221474)	Comparison Results
Steam Source pressure	50 to 80 psig Dynamic	50 to 80 psig Dynamic	Identical
Water Pressure	50 to 70 psig Dynamic	50 to 70 psig Dynamic	Identical
Air Pressure	60 to 80 psig Dynamic	60 to 80 psig Dynamic	Identical
Piping construction material	Brass	Brass	Identical
Fitting material	Copper	Copper	Identical

Summary of non-clinical testing

PRIMUS Healthcare Sterilizer (Models PSS11-HA and PSS11-HB) 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:

Test Methodology	Purpose	Acceptance Criteria	Results
Electrical Safety	To ensure that the device and its components meet the electrical safety requirements	Compliance with 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 the low 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	Compliance with standard ASME Boiler and pressure vessel code, Section VIII division 1	Pass

Test Methodology	Purpose	Acceptance Criteria	Results
	and is safe for use.		
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 both in-house and by outsourcing to appropriate third-party vendors.

The PRIMUS Healthcare Sterilizer complies 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 14971:2019 Medical devices - Application of risk management to medical devices
- ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices - Information to be supplied by the manufacturer.
- ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements information to be supplied - Part 1: General requirements.
- UL 508A, Edition 3 Industrial Control Panels

Summary of Clinical Testing

Clinical studies are not required for the PRIMUS Healthcare Sterilizer (Models PS11-HA and PSS11-HB).

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, effective, and performs as well as the legally marketed predicate device PRIMUS Healthcare Sterilizer (Model PSS11-HC) (K221474).