

1. General Information

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2. Device Name and Code

Device Trade Name: STERLINK™ FPS-15s Plus sterilizer with STERPACK™ plus cassette

Common Name: Vapor Phase Hydrogen Peroxide Sterilization System

Classification Name: Ethylene Oxide Gas Sterilizer

Product Code: MLR

Regulation Number: 880.6860

Classification: Class II

Review Panel: General Hospital

3. Device Description

The STERLINK™ FPS-15s Plus sterilizer with STERPACK™ plus cassette is a low temperature sterilizer which uses the STERLINK™ process to inactivate microorganisms on a broad range of medical devices and instruments.

This system consists of a main device and cassettes which are called the STERLINK™ FPS-15s Plus and STERPACK™ plus or STERLOAD™, respectively. The STERPACK™ plus and STERLOAD™ cassette contain 58-59.5% (weight concentration) of hydrogen peroxide (H₂O₂) which is utilized as the sterilant.

The sterilization cycle with STERLOAD™ was cleared under K212200. The focus of this application is on the additional sterilization cycle with STERPACK™ plus.

4. Indications / Intended Use

The STERLINK™ FPS-15s Plus sterilizer is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.

The STERLINK™ FPS-15s Plus can sterilize*:

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices with a single stainless-steel lumen with:
 - STERPACK™ plus: An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter
 - STERLOAD™: An inside diameter of 2.4 mm or larger and a length of 280 mm or shorter

*The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 1 lb and 3.97 lbs with STERPACK™ plus and STERLOAD™, respectively.

5. Technical Characteristics in Comparison to Predicate Devices

A summary of the technical characteristics of the subject device and predicate device can be found in the table below.

	Subject Device	Predicate Device
Manufacturer	Plasmapp Co., Ltd.	Same
Base Sterilizer	FPS-15s Plus	Same
510(k) Number	K223015	K212200
Device Classification Name	Ethylene oxide gas sterilizer	Same
Classification Product Code	MLR	Same
Regulation Number	21 CFR 880.6860	Same

	Subject Device	Predicate Device
Intended Use	<p>The STERLINK™ FPS-15s Plus sterilizer is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.</p> <p>The STERLINK™ FPS-15s Plus can sterilize*:</p> <ul style="list-style-type: none"> • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices with a single stainless-steel lumen with: <ul style="list-style-type: none"> o STERPACK™ plus: An inside diameter of 1.6 mm or larger and a length of 200 mm or shorter o STERLOAD™: An inside diameter of 2.4 mm or larger and a length of 280 mm or shorter <p>*The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 1 lb and 3.97 lbs with STERPACK™ plus and STERLOAD™, respectively.</p>	<p>The STERLINK™ FPS-15s Plus sterilizer with STERLOAD™ cassette is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed, and dried reusable metal and nonmetal medical devices used in healthcare facilities. A pre-programmed sterilization lumen cycle operates at low pressure and low temperature and is thus suitable for processing medical devices sensitive to heat and moisture.</p> <p>The STERLINK™ FPS-15s Plus can sterilize*:</p> <ul style="list-style-type: none"> • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices with a single stainless-steel lumen with: <ul style="list-style-type: none"> o An inside diameter of 2.4 mm or larger and a length of 280 mm or shorter <p>*The validation testing for all lumen sizes was conducted using a maximum of five (5) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load with a total weight of 3.97 lbs.</p>
Physical Characteristic	Self-contained, stand-alone device	Same
Design and Construction	Welded frame onto which is mounted the sterilization chamber along with a variety of instruments and components, controls, piping, and vacuum pump, all of which is housed in covered frame	Same
Chamber Volume	STERPACK™ plus :4.5 L STERLOAD™: 14 L	STERLOAD™: 14 L
Weight	147 lbs (67 kg)	Same
Max Power	1000 W	Same
Control System	Embedded Linux	Same
Internal process monitor		
Temperature	Chamber and vaporizer thermocouple	Same
Pressure	Chamber pressure transducers	Same
Sterilant Concentration	None	Same
Operational Principle	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time	Same

	Subject Device	Predicate Device
Devices	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture	Same
Sterilization Cycles	Two (2) pre-programmed cycles; STERPACK™ plus (approximately 14 minutes) and STERLOAD™ (approximately 36 minutes)	One (1) pre-programmed cycle; STERLOAD™ (approximately 36 minutes)
Sterilant		
Model Name	STERPACK™ plus and STERLOAD™	STERLOAD™
Type	Cassette type (unit dose)	Same
Sterilant	58-59.5% aqueous solution of hydrogen peroxide	Same
Monitoring accessories		
Biological Indicator	Self-contained biological indicator, <i>Geobacillus stearothermophilus</i>	Same
Process Challenge Device / Routine Test Pack	Self-contained biological indicator, <i>Geobacillus stearothermophilus</i>	Same
Chemical Indicator	Terragene® CI Strips and Tapes	Same
Miscellaneous (Sterilization wrap)		
Load Packaging	Tyvek® and PET/LLDPE film	Same

Technological differences between the STERLINK™ FPS-15s Plus sterilizer with STERPACK™ plus cassette and the predicate device are minimal and include:

- The subject device includes an additional cycle, the STERPACK™ plus cycle (total two pre-programmed sterilization lumen cycles), versus one cycle for the predicate device.
- The STERLINK™ FPS-15s Plus sterilizer with STERPACK™ plus cassette has a smaller sterilization volume and sterilant quantity compared to the predicate device.
- The sterilization chamber volume is smaller when the STERLINK™ FPS-15s Plus is utilized in pouch plus mode, as the sterilant only diffuses into the flexible chamber (i.e. pouch).
- When using the pouch plus mode of the STERLINK™ FPS-15s Plus, the medical devices must first be placed in a Tyvek® roll and then placed into the STERPACK™ plus pouch, as the STERPACK™ plus pouch is not a sterile barrier.

The STERLINK™ FPS-15s Plus sterilizer performance and safety characteristics have been shown to provide a level of safety and efficacy at least equivalent to that of the predicate device.

6. Performance Data

Non-clinical tests were performed using the following standards and/or guidance documents:

Test	Standard/Guidance Document	Result
Human factors and usability engineering	Guidance for Industry and Food and Drug Administration Staff, “Applying Human Factors and Usability Engineering to Medical Devices”, issued on February 3, 2016 IEC 62366-1:2015	Pass
Shelf-life test (Sterilant Preservation Test)	Manufacturer’s internal standard	1 year
Biocompatibility	ISO 10993-5:2009	Pass
Software validation	IEC 62304:2006 + AMD1:2015 Guidance for Industry and Food and Drug Administration Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Device”, issued on May 11, 2005	Pass
Electrical safety	EN 61010-1:2010 EN 61010-2-040:2015 IEC 60601-1:2005 (3rd Ed.) + CORR.1:2006 + CORR.2:2007 + A1:2012 EN 60601-1-2:2015	Pass
RF disturbance	EN 55011:2009/A1:2010	Pass
Electromagnetic compatibility (EMC)	EN 61326-1:2013 EN 61000-3-2:2014 EN 61000-3-3:2013 EN 60601-1-2:2015	Pass
Resistance validation for biological indicator test	ISO 11138-1:2017	Pass
Lumen sterilization	ISO 14937:2009	Pass
Surface sterilization	ISO 14937:2009 ISO 11737-1:2018 ISO 11737-2:2009	Pass
Mated surface sterilization	ISO 14937:2009 ISO 11737-1:2018 ISO 11737-2:2009	Pass
Simulated use test	ASTM E1837-96:2014 ISO 11737-1:2018	Pass
In-use test	ASTM E1837-96:2014	Pass
Sporicidal activity test	AOAC 966.04 (AOAC 6.3.05:2013)	Pass
Bacteriostasis test	ISO 11737-1:2018	Pass

Test	Standard/Guidance Document	Result
Material compatibility test	ASTM D638 ASTM E8/E8M-16ae1 ASTM D790 ASTM E290-14 ASTM D256 ASTM E23-18 ASTM E1164 ASTM E313 ASTM D3985 ASTM F1249	Pass
Delivery validation (Sterilizer)	ASTM D4169-14	Pass
Delivery validation (Sterilant)	Manufacturer's internal standard	Pass
Hydrogen peroxide gas detection test	OSHA analytical method 1019	Pass

7. Conclusions

The conclusions drawn from the nonclinical testing demonstrate that the device in 510(k) K223015, the STERLINK™ FPS-15s Plus sterilizer with STERPACK™ plus cassette, is as safe, as effective, and performs as well, or better, than the legally marketed predicate device cleared under K212200.