May 9, 2023

Plasmapp Co., Ltd.
% Candace Cederman
Consultant
CardioMed Device Consultants LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K223015
Trade/Device Name: STERLINK™ FPS-15s Plus sterilizer with STERPACK™ plus cassette
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: April 7, 2023
Received: April 10, 2023

Dear Candace Cederman:

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,

Christopher K. Dugard -S

for 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)*
K223015

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

Indications for Use *(Describe)*
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:
  - 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

*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.

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.

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1. General Information

Applicant/Submitter:	Plasmapp Co., Ltd. BVC-111, 125, Gwahak-ro, Yuseong-gu, Daejeon, 34141, Rep. of Korea (South Korea) Tel: +82 (0)42 716 2115
Contact Person: Address:	Candace Cederman CardioMed Device Consultants LLC 1783 Forest Drive Suite 254 Annapolis, MD 21401 Tel: +1 410 674 2060
Preparation Date:	May 4, 2023

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 (H_2O_2) 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	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: 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 *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.	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. 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: o 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 3.97 lbs.
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, *Geobacillus stearothermophilus*	Same
Process Challenge Device / Routine Test Pack	Self-contained biological indicator, *Geobacillus stearothermophilus*	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, "Appling 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.