May 25, 2023

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

Re: K231169
Trade/Device Name: STERLINK™ plus Sterilizer with STERLOAD™ Cassette, Tyvek Roll with CI for STERLINK™ Sterilizer, Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR, FRG, JOJ, FRC
Dated: April 24, 2023
Received: April 25, 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, Ph.D.
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)*
K231169

Device Name
STERLINK Plus Sterilizer with STERLOAD Cassette

Indications for Use *(Describe)*
The STERLINK 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 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.

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."

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)*
K231169

Device Name
Tyvek® Roll with CI for STERLINK Sterilizer

Indications for Use *(Describe)*

Tyvek® Roll with CI for STERLINK Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization.

The materials compatibility for use in the Tyvek® Roll with CI for STERLINK Sterilizer, when used in CHAMBER mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HPDE), Polypropylene (PP), Polytetrafluorethylene (PTFE) and Silicone (Hardness 50).

The maximum load weight that can be placed in the Tyvek® roll is:
- 3.97 pounds (1.8kg) for CHAMBER mode of FPS-15s Plus
- 3.97 pounds (1.8kg) for CHAMBER mode of STERLINK plus sterilizer
- 1.54 pounds (0.7kg) for CHAMBER mode of STERLINK mini sterilizer

The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1 :2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK sterilizer.

The Tyvek® Roll with CI for STERLINK Sterilizer is offered in the follow 1 type:
- Sterilization roll, Flat

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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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)*
K231169

Device Name
Terragene Bionova® SCBI (BT96), Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye® (CD42), and Terragene Cintape® (CT40)

Indications for Use *(Describe)*

Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 Geobacillus stearothermophilus bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60°C.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60°C and 37°C and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met.

Terragene Cintape® (CT40) is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with:

- CHAMBER mode of FPS-15s Plus sterilizer
- CHAMBER mode of STERLink plus sterilizer
- CHAMBER mode of STERLINK mini sterilizer

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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510(k) Summary for K231169
[as required by 21 CFR 807.92(c)]

STERLINK plus Sterilizer with STERLOAD™ Cassette
Tyvek® Roll with CI for STERLINK™ Sterilizer
Sterilization Process Indicator for STERLINK™ Sterilizer

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 22, 2023

Device Name and Code

Device Trade Name:	A. STERLINK plus Sterilizer with STERLOAD™ Cassette B. Tyvek® Roll with CI for STERLINK™ Sterilizer C. Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-bio), Terragene Chemdye (CD42), Terragene Cintape (CT40)
Common Name:	A. Vapor Phase Hydrogen Peroxide Sterilization System B. Tyvek® Roll for VH2O2 Sterilizer C. Self-contained Biological Indicator, Self-Contained Biological Indicator Incubator, Chemical Indicator.

Classification Name:	A. Ethylene Oxide Gas Sterilizer B. Sterilization Wrap C. Sterilization Process Indicator
Product Code:	A. MLR B. FRG, JOJ C. FRC, JOJ
Regulation Number:	A. 21 CFR 880.6860 B. 21 CFR 880.6850, 21 CFR 880.2800 C. 21 CFR 880.2800
Classification:	Class II
Review Panel:	General Hospital
Predicate Device:	STERLINK FPS-15s Plus Sterilizer with STERLOAD™ Cassette (K212200) Tyvek® Roll with CI for STERLINK™ Sterilizer (K212198) Terragene Bionova® SCBI (BT96), Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye® (CD42), Terragene Cintape® (CT40) – (K212193)

A. STERLINK plus Sterilizer with STERLOAD™ Cassette

A.1 Device Description

The STERLINK plus sterilizer with STERLOAD™ cassette is a low temperature sterilizer which uses the STERLINK™ process to inactivate microorganisms on a broad range of medical devices and instruments. This sterilizer offers an effective, safe, fast, economical, easy to use, reliable, and flexible sterilization method.

This system consists of a main device connected pump module and cassette which are called the STERLINK plus and STERLOAD™ cassette, respectively. The STERLOAD™ cassette contains 58-59.5% (weight concentration) of hydrogen peroxide (H_2O_2) which is utilized as the sterilant.

A.2 Indications / Intended Use

The Intended use of the subject device is identical to that of the predicate device cleared under K212200.

The STERLINK 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:
  - 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.

A.3 Technical Characteristics in Comparison to Predicate Devices

The STERLINK plus sterilizer is substantially equivalent to the following legally marketed predicate device.

	Subject Device	**Predicate Device**	**Substantially Equivalent or Difference**
Device Name (Model)	**STERLINK plus Sterilizer with STERLOAD™ Cassette**	**FPS-15s Plus Sterilizer with STERLOAD™ Cassette**	
510(k) Number	-	K212200	-
Product Code	MLR	MLR	Identical
Intended Use	The STERLINK 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 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:	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:	Identical

	Subject Device	Predicate Device	Substantially Equivalent or Difference
Device Name (Model)	**STERLINK plus Sterilizer with STERLOAD™ Cassette**	**FPS-15s Plus Sterilizer with STERLOAD™ Cassette**	
	- An inside diameter of 2.4 m m 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.	- 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	Self-contained, stand-alone device	Identical
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	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	Identical
Chamber Volume	14 L	14 L	Identical
Max Power	1000 W	1000 W	Identical
Weight	128 lbs. (58kg)	128 lbs. (58kg)	Identical
Control system	Embedded Linux	Embedded Linux	Identical
Software	IEC 62304	IEC 62304	Identical
Electrical Safety	IEC 60601-1 IEC 61010-1	IEC 60601-1 IEC 61010-1	Identical
Electromagnetic Compatibility (EMC)	IEC 60101-1-2	IEC 60101-1-2	Identical
Labeling	STERLINK plus product label, User manual	FPS-15s Plus product label, User manual	Differ only in name
Internal Process Monitor			
Temperature	Chamber and vaporizer thermocouple	Chamber and vaporizer thermocouple	Identical
Pressure	Chamber pressure transducers	Chamber pressure transducers	Identical
Operational Principle	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time	Sterilization of the intended devices by exposure under controlled conditions of pressure, temperature, and time	Identical
Operational Parameters	Low pressure (vacuum; sub-atmospheric down to 3 Torr) and temperature (60°C)	Low pressure (vacuum; sub-atmospheric down to 3 Torr) and temperature (60°C)	Identical

	Subject Device	Predicate Device	Substantially Equivalent or Difference
Device Name (Model)	**STERLINK plus Sterilizer with STERLOAD™ Cassette**	**FPS-15s Plus Sterilizer with STERLOAD™ Cassette**	
Pre-processing Requirements	Cleaned, rinsed, and dried devices	Cleaned, rinsed, and dried devices	Identical
Devices	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture	Reusable metal and non-metal medical devices that are used in healthcare facilities, including those that are sensitive to heat and moisture	Identical
Sterilization Cycles	One (1) pre-programmed; approximately 36 minutes	One (1) pre-programmed; approximately 36 minutes	Identical
Sterilant			
Model Name	STERLOAD™	STERLOAD™	Identical
Type	Cassette type (unit dose)	Cassette type (unit dose)	Identical
Sterilant	59% aqueous solution of hydrogen peroxide	59% aqueous solution of hydrogen peroxide	Identical
Monitoring Accessories			
Biological Indicator	Self-contained biological indicator, *Geobacillus stearothermophilus*	Self-contained biological indicator, *Geobacillus stearothermophilus*	Identical
Process Challenge Device / Routine Test Pack	Self-contained biological indicator, *Geobacillus stearothermophilus*	Self-contained biological indicator, *Geobacillus stearothermophilus*	Identical
Chemical Indicator	Terragene® CI Strips and Tapes	Terragene® CI Strips and Tapes	Identical
Miscellaneous (Sterilization wrap)			
Load Packaging	Tyvek® and PET/LLDPE film	Tyvek®/HDPE pouches	Substantially Equivalent

No technological differences exist between the subject and predicate devices. The two devices differ only in name.

A.4 Performance Data

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

Test	Standard/Guidance Document	Result
Risk management	ISO 14971	
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	Pass
Biocompatibility	ISO 10993-5	Pass

Test	Standard/Guidance Document	Result
Software validation	IEC 62304 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	IEC 60601-1 IEC 61010-1	Pass
Electromagnetic compatibility (EMC)	IEC 60601-1-2	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	Pass
Bacteriostasis test	ISO 11737-1:2018	Pass
Material compatibility test	ASTM D638 ASTM E8/E8M-16ae1 ASTM D790 ASTM E290-14 ASTM D256 ASTM E23-18 ASTM E1164 ASTM D3985 ASTM F1249	Pass
Delivery validation	ASTM D4169-14	Pass
Hydrogen peroxide gas detection test	OSHA analytical method 1019	Pass

B. Tyvek® Roll with CI for STERLINK™ Sterilizer

B.1 Device Description

Tyvek® Roll with CI for STERLINK™ Sterilizer is intended to be used to contain medical devices to be terminally sterilized in the STERLINK™ sterilization system. The medical devices are

inserted into the roll, sealed, and then sterilized in the STERLINK™ sterilization system. After completion of the sterilization process, the roll maintains sterility of the enclosed medical devices until the seal is opened. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices for up to 1 month post sterilization.

The roll is printed with a chemical indicator bar that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.

The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in one type as a Flat Sterilization roll. The sterilization roll is made from a Tyvek® sheet and a clear plastic film that are heat sealed together on opposite two sides. After being cut into a suitable length, the product to be sterilized is placed inside and the two open ends are heat sealed. The process indicator printed on the Tyvek® will exhibit a color change after the roll is exposed to hydrogen peroxide (H_2O_2).

B.2 Indications / Intended Use

The Intended use of the subject device is identical to that of the predicate device cleared under K212198.

> Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization.
>
> The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HPDE), Polypropylene (PP), Polytetrafluorethylene (PTFE) and Silicone (Hardness 50).
>
> The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.
>
> The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type:
>
> - Sterilization roll, Flat

B.3 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	Comparison
510(k) Sponsor	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Identical
Manufacturer	Sigma Medical Supplies Corp.	Sigma Medical Supplies Corp.	Identical
Device Name	Tyvek® Roll with CI for STERLINK™ Sterilizer	Tyvek® Roll with CI for STERLINK™ Sterilizer	Identical
510(k) Number	-	K212198	-
Device Classification Name	1) Sterilization Wrap 2) Sterilization Process Indicator	1) Sterilization Wrap 2) Sterilization Process Indicator	Identical
Classification Product Code	1) FRG 2) JOJ	1) FRG 2) JOJ	Identical
Regulation Number	1) 21 CFR 880.6850 2) 21 CFR 880.2800	1) 21 CFR 880.6850 2) 21 CFR 880.2800	Identical
Intended Use	Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization. The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in Chamber mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HDPE), Polypropylene (PP), Polytetrafluoroethylene (PTFE) and Silicone (Hardness 50). The maximum load weight that can be placed in the Tyvek® roll is 3.97 pounds (1.8 kg).	Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in CHAMBER mode, is intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERLINK™ sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 1 month post sterilization. The materials compatible for use in the Tyvek® Roll with CI for STERLINK™ Sterilizer, when used in Chamber mode, are as follows: Aluminum 5052, Aluminum 6061, Stainless Steel 304, Stainless Steel 316L, Titanium, Acrylonitrile Butadiene Styrene (ABS), High Density Polyethylene (HDPE), Polypropylene (PP), Polytetrafluoroethylene (PTFE) and Silicone (Hardness 50). The maximum load weight that can be placed in the Tyvek® roll is 3.97 lbs. (1.8 kg). The roll is printed with a chemical indicator bar which is a process	Identical

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th><th>Comparison</th></tr>
<tr><td></td><td>The roll is printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.

The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type:
• Sterilization roll, Flat</td><td>indicator (ISO 11140-1:2005) that changes from red to blue (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERLINK™ sterilizer.

The Tyvek® Roll with CI for STERLINK™ Sterilizer is offered in the follow 1 type:
• Sterilization roll, Flat</td><td></td></tr>
<tr><td>Pouch Types</td><td>Sterilization roll, Flat</td><td>Sterilization roll, Flat</td><td>Identical</td></tr>
<tr><td>Device models (Configurations /Dimensions)</td><td><table><tr><th colspan="2">Sterilization Roll, Flat</th></tr><tr><td>Model</td><td>Dimensions</td></tr><tr><td>FR400100</td><td>400 mm × 100 M</td></tr></table></td><td><table><tr><th colspan="2">Sterilization Roll, Flat</th></tr><tr><td>Model</td><td>Dimensions</td></tr><tr><td>FR400100</td><td>400 mm × 100 M</td></tr></table></td><td>Identical</td></tr>
<tr><td>Material Composition</td><td>Tyvek®, PET, PE, Water, CH_3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink</td><td>Tyvek®, PET, PE, Water, CH_3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink</td><td>Identical</td></tr>
<tr><td>Sterilization Cycle</td><td>STERLINK plus - Chamber mode (overall cycle: 36 minutes)</td><td>STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes)</td><td>Identical</td></tr>
<tr><td>Design Feature</td><td>Sterilization roll, Flat: This roll is made from a Tyvek® and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the Tyvek® are the same with the self-sealing sterilization roll.</td><td>Sterilization roll, Flat: This roll is made from a Tyvek® and plastic film that are heat sealed on opposite two sides. It will be cut into the suitable length and the opened sides will be heat-sealed. The indicators printed on the Tyvek® are the same with the self-sealing sterilization roll.</td><td>Identical</td></tr>
<tr><td>Chemical Indicator Device Design</td><td>The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.</td><td>The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.</td><td>Identical</td></tr>
</table>

B.4 Performance data

The Tyvek® Roll with CI for STERLINK™ Sterilizer has the identical intended use and indication for use as the predicate device. Both the size and material of subject device are same as the predicate device.

There are no changes to the mechanical constructions of the device between FPS-15s Plus and STERLINK plus that would impact previously executed performance and safety test.

Performance Testing		Standard
Sterilant Penetration	Sterilization efficacy test	ISO 14937:2009
	CI of sterilization roll validation	ANSI/AAMI/ISO 11140-1:2014
Shelf-life	Internal pressurization test	ASTM F1980-16:2016 ASTM F1140/F1140M-13:2013
	Visual inspection test	ASTM F1980-16:2016 ASTM F1886/F1886M-16:2016
	Dye penetration test	ASTM F1980-16:2016 ASTM F1929-15:2015
	Tensile strength of Tyvek®	ASTM F1980-16:2016 ASTM D5035-11:2019
	Tensile strength of plastic film	ASTM F1980-16:2016 ASTM D882
	Seal strength	ASTM F1980-16:2016 ASTM F88
	Tear resistance	ASTM F1980-16:2016 ASTM D1922-20
	Microbial Barrier Test	ASTM F1980-16:2016 DIN 58953-6:2016
	CI of sterilization roll validation	ANSI/AAMI/ISO 11140-1:2014
Residual sterilant on Tyvek® validation		Internal test standard

C. Sterilization Process Indicator for STERLINK™ Sterilizer

C.1 Device Description

Terragene® Bionova® BT96 Fluorescence Super Rapid Readout Biological Indicators are single-use Self-Contained Biological Indicators (SCBIs) that consist of a polypropylene tube, a spore carrier, and a glass ampoule with a culture medium, enclosed with a colored cap. Each tube contains a population of *Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a spore carrier, a plastic cap with holes and a barrier permeable to Plasma or Vaporized Hydrogen Peroxide. Each BT96 has a Process Indicator on label that changes from purple to green when exposed to hydrogen peroxide. The Bionova® BT96 Biological Indicators have been designed for monitoring of Vaporized Hydrogen Peroxide sterilization processes when used in conjunction with Bionova® IC10/20FRLCD or Mini-Bio Auto-Readers Incubators.

Chemdye® CD42 Process Indicators (Type 1 according to ISO 11140-1:2014 standard) are single-use chemical indicators that consist of plastic strips printed with indicator ink. These indicators have been designed to monitor Plasma or Vaporized Hydrogen Peroxide sterilization processes

within loads, ensuring an adequate exposure to the sterilizing agent during the sterilization process and allowing to distinguish between processed and unprocessed items.

Cintape® CT40 Process Indicators (Type 1 according to ISO 11140-1:2014 standard) are single-use chemical indicators that consist of a roll of self-adhesive plastic tape printed with indicator ink. These indicators have been designed to monitor Plasma or Vaporized Hydrogen Peroxide sterilization processes, ensuring an adequate exposure to the sterilizing agent during the sterilization process and allowing to distinguish between processed and unprocessed items.
The adhesive component of the tape allows the adhesion to different types of packaging and wraps, such as cloth, paper, and plastic.

C.2 Indications for Use / Intended Use

The subject and predicate device have the same intended use. The specific indications for use differ only in the identification of the appropriate sterilization cycles. The revised indications for use are as follows:

Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60°C.

Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60°C and 37°C and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow to indicate that the conditions of the cycle have been met.

Terragene Cintape® (CT40) is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide.

The self-contained biological indicator and chemical processing indicators are intended for use with:

- CHAMBER mode of FPS-15s Plus sterilizer
- CHAMBER mode of STERLINK plus sterilizer
- CHAMBER mode of STERLINK mini

C.3 Technical Characteristics in Comparison to Predicate Devices

The sterilization process indicators for the STERLINK™ sterilizer are identical to the predicate devices cleared under K212193.

	Subject Device	Predicate Device	Comparison
Sponsor	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Identical
Device Name	Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40)	Terragene Bionova® SCBI (BT96); Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio); Terragene Chemdye® (CD42); Terragene Cintape® (CT40)	Identical
510(k) Number	-	K212193	-
Manufacturer	Terragene® S.A.	Terragene® S.A.	Identical
Device Classification Name	Sterilization Process Indicator	Sterilization Process Indicator	Identical
Classification Product Code	FRC (biological indicators) JOJ (chemical indicators)	FRC (biological indicators) JOJ (chemical indicators)	Identical
Regulation Number	21 CFR 880.2800	21 CFR 880.2800	Identical

	Subject Device	Predicate Device	Comparison
Sponsor	Plasmapp Co., Ltd.	Plasmapp Co., Ltd.	Identical
Indications for Use	Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60ºC. Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60ºC and 37ºC and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals. Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met. Terragene Cintape® (CT40) is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide. The self-contained biological indicator and chemical processing indicators are intended for use with the STERLINK plus when operating in chamber mode.	Terragene Bionova® SCBI (BT96) is a self-contained biological indicator inoculated with viable 10^6 *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 has Super Rapid readout at 30 minutes at 60ºC. Terragene Bionova® Reader Incubators (IC10/20FRLCD, Mini-Bio) incubate at 60ºC and 37ºC and read the Terragene Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals. Terragene Chemdye® (CD42) is a chemical process indicator intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. The chemical indicator changes from red to yellow for CD42 to indicate that the conditions of the cycle have been met. Terragene Cintape® CT40 is a chemical process indicator tape intended for monitoring the efficacy of Vaporized Hydrogen Peroxide sterilization processes. The indicating tape changes from purple to green when exposure to vaporized hydrogen peroxide. The self-contained biological indicator and chemical processing indicators are intended for use with the STERLINK™ FPS-15s Plus when operating in chamber mode.	Identical

	Subject Device		Predicate Device		Comparison
Sponsor	Plasmapp Co., Ltd.		Plasmapp Co., Ltd.		Identical
Intended Use: Cycles	Models	Cycle	Models	Cycle	Identical cycles Differ only in name
	BT96	STERLINK plus-Chamber mode	BT96	STERLINK FPS-15s plus-Chamber mode	
	CD42		CD42		
	CT40		CT40		
Terragene Bionova® SCBI (BT96)					
Type of Biological Indicator	Self-Contained		Self-Contained		Identical
Organism Spore Species Strain	*Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a strip (spore carrier)		*Geobacillus stearothermophilus* ATCC 7953 spores inoculated on a strip (spore carrier)		Identical
Viable Spore Population	$\geq 10^6$		$\geq 10^6$		Identical
Resistance characteristics	*D*-value Survival time/Kill window		*D*-value Survival time/Kill window		Identical
Intended Sterilization Cycles	STERLINK plus - Chamber mode (overall cycle: 36 minutes)		STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes)		Identical
Shelf Life	2 years		2 years		Identical
Terragene Chemdye® (CD42), Terragene Chemdye® (CT40)					
Intended Sterilization Cycles	STERLIN plus - Chamber mode (overall cycle: 36 minutes)		STERLINK™ FPS-15s Plus – Chamber mode (overall cycle: 36 minutes)		Identical
Device design	Strip, Tape		Strip, Tape		Identical
Color Change upon Exposure to H_2O_2	CD42: red to yellow CT40: purple to green		CD42: red to yellow CT40: purple to green		Identical
Recommended Storage Conditions	Dry place, away from sunlight, at temperature between 10-30ºC, 30-80% relative humidity. Do not wet. Do not store close to sterilizing agents.		Dry place, away from sunlight, at temperature between 10-30ºC, 30-80% relative humidity. Do not wet. Do not store close to sterilizing agents.		Identical
Shelf Life	5 years		5 years		Identical
The subject and predicate devices are identical with respect to the organism, accessories, spore population, resistance characteristics, culture conditions, carrier materials, packaging, storage conditions and claimed shelf life. The only difference between the subject and predicate devices are the proposed indications for use, to label the indicators for use with the STERLINK plus when operating in chamber mode.					

C.4 Performance Data

Non-clinical tests were performed using following standards:

Item	Test	Standard/Guidance Document	Result
Self-Contained Biological Indicator (BT96)	Resistance validation for biological indicator test	ISO 11138-1:2017	Pass
	BI & Test pack validation test	Manufacturer's internal standard	Pass
Chemical Indicator (CD42, CT40)	Chemical indicator validation	Manufacturer's internal standard	Pass

Clinical Data:

This submission does not contain any data from clinical testing.

Conclusions

The conclusions drawn from the nonclinical testing demonstrate that the subject devices, STERLINK plus Sterilizer with STERLOAD Cassette, Tyvek Roll with CI for STERLINK Sterilizer and Sterilization Process Indicator for STERLINK Sterilizer: Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye (CD42) and Terragene Cintape (CT40) are as safe, as effective, and perform as well as or better than the legally marketed predicate devices: STERLINK FPS-15s Plus Sterilizer with STERLOAD Cassette, Tyvek Roll with CI for STERLINK Sterilizer, Terragene Bionova SCBI (BT96), Terragene Bionova Reader Incubators (IC10/20FRLCD, Mini-Bio), Terragene Chemdye (CD42), and Terragene Cintape (CT40)