October 22, 2021

Consultant
CardioMed Device Consultants LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K212198
Trade/Device Name: Tyvek® Roll with CI for STERLINK™ Sterilizer
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: September 20, 2021
Received: September 21, 2021

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212198

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 maximum load weight that can be placed in the Tyvek® roll is 3.97 pounds (1.8kg).

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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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:	Candace Cederman
Address:	CardioMed Device Consultants LLC 1783 Forest Drive Suite 254 Annapolis, MD 21401 Tel: +1 410 674 2060
Preparation Date:	October 12, 2021

2. Device Name and Code

Device Trade Name:	Tyvek® Roll with CI for STERLINK™ Sterilizer
Common Name:	Tyvek® Roll for VH2O2 Sterilizer
Classification Name:	1) Sterilization Wrap 2) Sterilization Process Indicator
Product Code:	1) FRG 2) JOJ
Regulation Number:	1) 21 CFR 880.6850 2) 21 CFR 880.2800
Classification:	Class II
Review Panel:	General Hospital

3. Indications / 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 maximum load weight that can be placed in the Tyvek® roll is 3.97 pounds (1.8kg).

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

4. 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).

5. Technical Characteristics in Comparison to Predicate Devices

The proposed subject device uses identical technology as the cited predicate devices and has the same intended uses. Based upon the overall performance characteristics for Tyvek® Roll with CI for STERLINK™ Sterilizer, Plasmapp Co., Ltd. believes there are no significant differences in

usage of its underlying technological principles between Tyvek® Roll with CI for STERLINK™ Sterilizer and the predicate device.

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

Summary of Subject and Predicate Device Technical Characteristics

	Subject Device	**Predicate Device**
510(k) Sponsor	Plasmapp Co., Ltd.	Sigma Medical Supplies Corp.
Manufacturer	Sigma Medical Supplies Corp.	Same
Device Name	Tyvek® Roll with CI for STERLINK™ Sterilizer	Sterilization Pouch/Roll Made with Tyvek®
510(k) Number	K212198	K180672
Device Classification Name	1) Sterilization Wrap 2) Sterilization Process Indicator	Same
Classification Product Code	1) FRG 2) JOJ	Same
Regulation Number	1) 21 CFR 880.6850 2) 21 CFR 880.2800	Same
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 maximum load weight that can be placed in the Tyvek® roll is 3.97lbs (1.8kg). 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	Sterilization Pouch/Roll Made with Tyvek® are intended to provide health care workers with an effective method to enclose devices intended for sterilization in the STERRAD® 100S Sterilizer. The device is intended to allow sterilization of enclosed devices and also to maintain sterility of the enclosed devices until used up to 3 years post sterilization. The pouches and rolls are 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 STERRAD® 100S Sterilizer. The Sterilization Pouch/Roll Made with Tyvek® is offered in the follow 5 types: • Self-sealing sterilization pouches • Sterilization pouches, Flat • Sterilization pouches, Gusseted • Sterilization rolls, Flat • Sterilization rolls, Gusseted
Pouch Types	The subject device includes a subset of the predicate device types: - Sterilization roll, Flat	- Self-sealing sterilization pouches - Sterilization pouches, Flat - Sterilization pouches, Gusseted - Sterilization rolls, Flat - Sterilization rolls, Gusseted

<table>
<tr><th></th><th>Subject Device</th><th>Predicate Device</th></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>
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<table>
<tr><th colspan="2">Sterilization Pouches, Flat</th></tr>
<tr><td>Model</td><td>Dimensions</td></tr>
<tr><td>TYFP075200</td><td>75 mm × 200 mm</td></tr>
<tr><td>TYFP075300</td><td>75 mm × 300 mm</td></tr>
<tr><td>TYFP100200</td><td>100 mm × 200 mm</td></tr>
<tr><td>TYFP100300</td><td>100 mm × 300 mm</td></tr>
<tr><td>TYFP150255</td><td>150 mm × 255 mm</td></tr>
<tr><td>TYFP150300</td><td>150 mm × 300 mm</td></tr>
<tr><td>TYFP190330</td><td>190 mm × 330 mm</td></tr>
<tr><td>TYFP200400</td><td>200 mm × 400 mm</td></tr>
<tr><td>TYFP250450</td><td>250 mm × 450 mm</td></tr>
<tr><td>TYFP300500</td><td>300 mm × 500 mm</td></tr>
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<tr><th colspan="2">Sterilization Rolls, Flat</th></tr>
<tr><td>Model</td><td>Dimensions</td></tr>
<tr><td>TYFR050070</td><td>50 mm × 70 M</td></tr>
<tr><td>TYFR022f</td><td>50.8 mm × 61 M</td></tr>
<tr><td>TYFR075070</td><td>75 mm × 70 M</td></tr>
<tr><td>TYFR100070</td><td>100 mm × 70 M</td></tr>
<tr><td>TYFR042f</td><td>101.6 mm × 61 M</td></tr>
<tr><td>TYFR150070</td><td>150 mm × 70 M</td></tr>
<tr><td>TYFR062f</td><td>152.4 mm × 61 M</td></tr>
<tr><td>TYFR200070</td><td>200 mm × 70 M</td></tr>
<tr><td>TYFR082f</td><td>203.2 mm × 61 M</td></tr>
<tr><td>TYFR250070</td><td>250 mm × 70 M</td></tr>
<tr><td>TYFR102f</td><td>254 mm × 61 M</td></tr>
<tr><td>TYFR300070</td><td>300 mm × 70 M</td></tr>
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<tr><td>TYFR400070</td><td>400 mm × 70 M</td></tr>
<tr><td>TYFR450070</td><td>450 mm × 70 M</td></tr>
<tr><td>TYFR500070</td><td>500 mm × 70 M</td></tr>
<tr><td>TYFR050100</td><td>50 mm × 100 M</td></tr>
<tr><td>TYFR075100</td><td>75 mm × 100 M</td></tr>
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<tr><td>TYFR400200</td><td>400 mm × 200 M</td></tr>
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	Subject Device	Predicate Device
Material Composition	Tyvek®, PET, PE, Water, CH_3COOH, Alcohol, n-Heptane adhesive, Hydrogen peroxide vapor Process Indicator Print Ink	Same
Sterilization Cycle	STERLINK™ FPS-15s Plus - Chamber mode (overall cycle: 36 minutes)	STERRAD® 100S sterilization cycles: • 54-minute Short cycle for most surgical instruments • 72-minute Long cycle for flexible endoscopes and instruments with longer lumen
Design Feature	**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.	Same
Chemical Indicator Device Design	The color of the Chemical Indicator changes from red to blue (or lighter) when exposed to hydrogen peroxide.	Same

6. Summary of Non-Clinical Testing

The Tyvek® Roll with CI for STERLINK™ Sterilizer has the identical intended use and indication for use as the predicate devices. Testing of the roll material was previously conducted on the predicate K180672. The identical materials are used in the Tyvek® Roll with CI for STERLINK™ Sterilizer. The size of the subject device is within the range of sizes available for the predicate device.

The performance and safety test of subject device was evaluated using the STERLINK™ FPS-15s Plus system, operating in Chamber mode, following the standards listed in the table below.

Performance Testing		Standard	Result
Sterilant Penetration	Sterilization efficacy test	ISO 14937	Pass
	CI of sterilization roll validation	ANSI/AAMI/ISO 11140-1	Pass
Shelf-life	Internal pressurization test	ASTM F1980-16 ASTM F1140/F1140M-13	Pass
	Visual inspection test	ASTM F1980-16 ASTM F1886/F1886M-16	Pass
	Dye penetration test	ASTM F1980-16 ASTM F1929-15	Pass
	Tensile strength of Tyvek®	ASTM F1980-16 ASTM D5035-11	Pass
	Tensile strength of plastic film	ASTM F1980-16 ASTM D882	Pass
	Seal strength	ASTM F1980-16 ASTM F88	Pass

Performance Testing		Standard	Result
	Tear resistance	ASTM F1980-16 ASTM D1922-20	Pass
	Microbial Barrier Test	ASTM F1980-16 DIN 58953-6	Pass
	CI of sterilization roll validation	ANSI/AAMI/ISO 11140-1	Pass
Toxicological Properties (Biocompatibility Tests)		ISO 10993-5	Pass - Test article is non-cytotoxic after the sterilization.
Residual sterilant on Tyvek® validation		Internal test standard	Pass
Material compatibility test		ASTM D638 ASTM E8/E8M-ae1 ASTM D790 ASTM E290-14 ASTM D256 ASTM E23-18 ASTM E1164 ASTM E313 ASTM D3985 ASTM F1249 Internal test standard	Pass

7. Conclusions

The conclusions drawn from the non-clinical tests demonstrates that the subject device in 510(k) submission K212198, Tyvek® Roll with CI for STERLINK™ Sterilizer, is as safe, as effective, and performs as well or better than the legally marketed predicate device cleared under K180672.