October 27, 2021

Synovis Life Technologies. Inc. (A Subsidiary Of Baxter International Inc.)
Megan Sajjad
Senior Manager, Regulatory Affairs
2575 University Ave. W
St. Paul, Minnesota 55114

Re: K213125
Trade/Device Name: PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OXE
Dated: September 24, 2021
Received: September 27, 2021

Dear Megan Sajjad:

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 and Part 809); 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,

for Deborah Fellhauer, RN, BSN
Assistant Director (acting)
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)*

K213125

Device Name
PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology

Indications for Use *(Describe)*

PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

PSDV-SG can be used for reinforcement of staple lines during bariatric, gastric, small bowel, colon and colorectal procedures.

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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PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology SPECIAL 510K

510(k) Summary

PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology

I. SUBMITTER

Synovis Life Technologies, Inc.
(A Subsidiary of Baxter International Inc.)
2575 University Avenue West
St. Paul, MN 55114-1024

Contact Person**:** Megan Sajjad, Sr. Manager, Regulatory Affairs
Phone: 651-796-7410

Date Prepared: September 24, 2021

II. DEVICE

Device Name:	PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology
Common Name:	Staple Line Reinforcement
Classification Name:	MESH, SURGICAL; MESH, SURGICAL, COLLAGEN, STAPLE LINE REINFORCEMENT
Regulation Number	21 CFR 878.3300
Product Codes:	FTM, OXE

III. PREDICATE DEVICE

PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology, K192615.

This predicate has not been subject to any market recalls.

IV. DEVICE DESCRIPTION

PERI-STRIPS DRY Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology is prepared from dehydrated bovine pericardium procured from cattle under 30 months of age, originating from the United States.

There are two types of PSDV-SG configurations based on the tissue buttress thickness range. The Standard configuration has a tissue buttress thickness range of 0.20-0.60mm. The Thin configuration has a tissue buttress thickness range of 0.20-0.40mm.

The product consists of a loading unit which includes two (2) buttresses, one for the anvil and one for the cartridge side of the stapler. The buttresses are held in a foam/sheath configuration for loading of the buttress to the stapler jaws. Each buttress has acrylic adhesive

on one side for attachment to the stapler surfaces. Each PSDV-SG loading unit is packaged sterile in a separate pouch.

PSDV-SG utilizes animal tissue; patient must be informed prior to any procedure.

PSDV-SG is provided sterile and intended for single use. Sterilization is accomplished via ethylene oxide (ETO). The bovine pericardium buttress and acrylic adhesive are considered permanent implants per ISO 10993-1 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*.

V. INTENDED USE/INDICATIONS FOR USE

The Intended Use and Indications for Use remain the same as the predicate device.

Intended Use:
PSDV-SG is intended to be used as a staple line buttress.

Indications for Use:
PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

PSDV-SG can be used for reinforcement of staple lines during bariatric, gastric, small bowel, colon, and colorectal procedures.

VI. TECHNOLOGICAL CHARACTERISTICS AND COMPARISON WITH THE PREDICATE DEVICE

PSDV-SG products are implantable biologic meshes comprised of non-cross-linked bovine pericardium. PSDV-SG is the VERITAS Collagen Matrix (K002233) tissue that has been dried and cut to specification for use with staplers to provide buttress reinforcement at the staple line. PSDV-SG allows for neo-collagen formation and neo-vascularization of the implanted device and permits replacement of the device with host tissue, or remodeling.

The technological characteristics and specifications of PSDV-SG have been evaluated against its predicate device to determine equivalence. A summary of the comparison between the predicate and subject devices is provided Table 5-1 below.

Table 5-1. PSDV-SG Predicate and Subject devices - Comparison Table

Attribute	Predicate Device	Subject Device
Product Name	PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology	SAME
510(k)-holder	Synovis Life Technologies, Inc. (A Subsidiary of Baxter International Inc.)	SAME
510(k) Number	K192615	K213125
Product Code	FTM, OXE	SAME
Regulation	21 CFR 878.3300	SAME
Classification	Class II	SAME
Intended Use	PSDV-SG is intended to be used as a staple line buttress.	SAME
Indications for Use	PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology is intended for	SAME

Attribute	Predicate Device	Subject Device
	use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed. PSDV-SG can be used for reinforcement of staple lines during bariatric, gastric, small bowel, colon and colorectal procedures.	
Tissue	Bovine pericardium procured from cattle under 30 months of age, originating from the United States	SAME
Components	Tissue strips, adhesive, liner pull tab, loading unit (foam, sheath), ship clip and packaging (inner pouch, outer pouch, labeling and carton)	SAME
Thickness per Firing (mm)	Standard: 0.45 – 1.26 Thin: 0.45 – 0.86	SAME
Principle of Operation	Non–cross-linked collagen tissue technology allows for neo-collagen formation and neovascularization of the implanted device and permits infiltration of the device with host tissue, or remodeling. PSDV-SG is designed to provide strength throughout the healing process, particularly where remodeling with the patient's' own tissue is preferred.	SAME
Stapler Compatibility	Ethicon Echelon ENDOPATH Staplers (K163454, K160521, K140560)	Medtronic Endo GIA Staplers (K111825) and Intuitive Surgical SureForm Staplers (K173721)
How Supplied	Single-use Sterile	SAME
Packaging	Sterile double pouch	SAME
Sterilization	ETO	SAME
Shelf-life	3 years	1 year with testing to 3 years ongoing

VII. PERFORMANCE DATA

Testing performed to support the new product models subject of this submission included manipulation, functional, and dimensional testing, as well as usability and shelf-life. Materials evaluation was not necessary as the new models are manufactured and packaged utilizing the same materials and components, from the same suppliers, used with the predicate device.

VIII. CONCLUSION

The PSDV-SG product family maintains the same intended use, indications for use, materials, and principles of operation. The line extension introducing new product models does not impact these product characteristics. The differences in size and design are made for stapler compatibility. Verification and validation of the product have been completed using the same test methods as the predicate device, or accepted industry standard methods. No new issues of safety and effectiveness have been identified.

The new PSDV-SG models have been found substantially equivalent to the predicate device with respect to intended use, design, materials, principle of operation and overall technological characteristics.