December 17, 2019

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

Re: K192615
Trade/Device Name: Peri-Strips Dry with Veritas Collagen Matrix with Secure Grip Technology (PSDV-SG)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OXE
Dated: September 20, 2019
Received: September 23, 2019

Dear Ms. 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); 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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting 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)*
K192615

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 (PSDV-SG) 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.0 510(K) SUMMARY: PERI-STRIPS Dry Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology

I. SUBMITTER

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

Contact Person**:** Megan Sajjad, Manager, Regulatory Affairs
Tel: 651-796-7410

Date Prepared: September 20, 2019

II. DEVICE

Device Trade Name: PERI-STRIPS Dry with VERITAS Collagen Matrix with SECURE GRIP Technology

Common Name: Staple Line Reinforcement

Classification Name: MESH, SURGICAL; MESH, SURGICAL, COLLAGEN, STAPLE LINE REINFORCEMENT (21 CFR 878.3300)

Product Code: FTM, OXE

III. PREDICATE DEVICES

Primary Predicate:
PERI-STRIPS Dry with VERITAS Collagen Matrix Staple Line Reinforcement, K041669

Additional Predicate:
PERI-STRIPS Dry Circular Staple Line Reinforcement with VERITAS Collagen Matrix, K083039

IV. DEVICE DESCRIPTION

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

The product consists of a loading unit which includes two (2) buttresses, one for the anvil **(ANV)** and one for the cartridge **(CART)** side of the stapler. 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.

See Table 1 for product models and configurations.

Table 1. PSDV-SG Model Numbers and Sizes

Model Number	Size (mm)	Thickness (mm) per Firing	Stapler Compatibility
PSDA60ECH	60	0.45 – 1.26	Ethicon Echelon 60 ENDOPATH Stapler Ethicon Echelon FLEX 60 ENDOPATH Stapler
PSDA60ECHTHN	60	0.45 – 0.86	Ethicon Echelon 60 ENDOPATH Stapler Ethicon Echelon FLEX 60 ENDOPATH Stapler

PSDV-SG is provided sterile and intended for single use. Sterilization occurs via ethylene oxide. The bovine pericardium buttress and acrylic adhesive are intended for permanent implant.

V. INTENDED USE/INDICATIONS FOR USE

Statement of Intended Use:

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

Indications for Use

PSDV-SG 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.

The Indications for Use for the PSDV-SG product are not identical to the predicate devices, however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. Both the subject and predicate devices have the same intended use for staple line buttressing.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Peri-Strips Dry with Veritas (PSDV) product family are implantable biologic meshes comprised of non-cross-linked bovine pericardium. PSDV 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

allows for neo-collagen formation and neo-vascularization of the implanted device and permits replacement of the device with host tissue, or remodeling.

PSDV-SG is substantially equivalent to the predicates PERI-STRIPS Dry with VERITAS Collagen Matrix Staple Line Reinforcement (PSDV-L) (K041669) and PERI-STRIPS Dry Circular Staple Line Reinforcement with VERITAS Collagen Matrix (PSDV-C) (K083039) based on having the same fundamental technology and intended use. The PSDV-SG product modifies the current PSDV-L product by replacing the hydrogel accessory component, used for the securement of the PSDV-L tissue buttress to a surgical stapler, with a pre-applied adhesive strip. The pre-applied adhesive strip is protected by a removable liner with pull tab until time of use. The adhesive strip being added is the same material that is used in the current PSDV-C product.

The subject and predicate devices are identical in the following respects:

- Same Intended Use (PSDV-L and PSDV-C)
- Same buttress material (PSDV-L and PSDV-C)
- Same adhesive material (PSDV-C)
- Same tissue dimensions, loading unit and stapler compatibility (PSDV-L 60 ECH configuration)
- Same packaging materials (PSDV-L)
- Same method of sterilization (PSDV-L and PSDV-C)

The following technological differences exist between the subject and predicate devices:

- Different mechanism of attachment of the tissue buttress to stapler compared to PSDV-L
- Different adhesive coat weight and dimensions compared to PSDV-C
- Narrowed indications for use compared to the cleared indications for PSDV-L and PSDV-C

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Pre-Clinical Bench Studies

Design verification of the PSDV-SG device consisted of the following assessments:

- Visual Inspection
- Thickness
- Functional Testing
- Manipulation Testing
- Chemical residuals
- Drape

- Heavy Metals
- Endotoxin
- Bioburden
- Sterilant residuals
- Seal strength of packaging seals
- Preparation time
- Stackability

The results of new bench testing, along with applicable historical testing utilizing PSDV-L or PSDV-C, demonstrate the performance of the PSDV-SG device is substantially equivalent to the predicate devices.

Biocompatibility

All patient contacting materials found in the PSDV-SG device have been previously cleared under Synovis premarket notifications K041669 and K083039. In order to confirm that modifications in the manufacturing process of PSDV-SG have no impact on the biocompatibility of the device, confirmatory cytotoxicity testing was conducted according to ISO 10993-5:2009 L929 elution method. Testing passed the acceptance criteria.

Shelf Life

Synovis has performed aging testing to support a 6 month shelf life claim. Testing at additional timepoints is ongoing and the product shelf life will be extended as stability data justifies.

Sterilization

PSDV-SG will be adopted into the existing sterilization cycle for PSDV-L and PSDV-C per AAMI TIR28:2016 *Product adoption and process equivalence for ethylene oxide sterilization.*

Validation Studies

A human factors study was successfully completed demonstrating the usability of the product and user comprehension of the labeling. A surgeon validation was additionally completed and supports customer satisfaction of the PSDV-SG functionality.

VIII. CONCLUSION

PSDV-SG shares the same intended use and technological characteristics as the predicate devices. The physical, functional and performance specifications for the device are substantially equivalent. There are no different questions of safety and effectiveness of PSDV-SG as compared to the predicate devices. Testing supports that PSDV-SG is as safe and effective as the predicate PSDV-L and PSDV-C devices when used according to its labeling.