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

Re: K223052
Trade/Device Name: Peri-Guard and Supple Peri-Guard
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: March 27, 2023
Received: March 28, 2023

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); 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,

Deborah A. Fellhauer -S

Deborah Fellhauer, RN, BSN
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)*
K223052

Device Name
PERI-GUARD Repair Patch
SUPPLE PERI-GUARD Repair Patch

Indications for Use *(Describe)*
PERI-GUARD is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, scrotal, and umbilical hernias).

SUPPLE PERI-GUARD is intended for use as a prosthesis for soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, scrotal, and umbilical hernias).

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."

510k SUMMARY: PERI-GUARD Repair Patch and SUPPLE PERI-GUARD Repair Patch

I. SUBMITTER

Synovis Life Technologies, Inc. (Synovis)
(A Subsidiary of Baxter International Inc.)
2575 University Avenue West
St. Paul, MN 55114-1024
Phone: 651-796-7410
Fax: 224-270-4119

Contact Person**:** Megan Sajjad, Sr. Manager, Regulatory Affairs

Date prepared: March 27, 2023

II. DEVICE

Device Trade Names: PERI-GUARD and SUPPLE PERI-GUARD

Common Name: Repair Patch

Regulation: 21 CFR 878.3300 - Surgical Mesh

Product Codes: FTM (Mesh, Surgical), OWV (mesh, surgical, collagen, diaphragmatic hernia), OXB (mesh, surgical, collagen, thoracic, chest wall reconstruction);

III. PREDICATE DEVICE

PERI-GUARD Repair Patch and SUPPLE PERI-GUARD Repair Patch, K983162
Manufacturer: Synovis Life Technologies, Inc., (A Subsidiary of Baxter International Inc.)

Additionally, Synovis PERI-GUARD Repair Patch and SUPPLE PERI-GUARD Pericardium Patch (K142447) and PERI-STRIPS DRY Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology (K192615) serve as Reference devices for this 510k.

IV. DEVICE DESCRIPTION

PERI-GUARD Repair Patch (PERI-GUARD) and SUPPLE PERI-GUARD Repair Patch (SUPPLE PERI-GUARD) are derived from bovine pericardium procured from cattle originating in the United States. The pericardium is cross-

linked with glutaraldehyde and treated with 1 molar sodium hydroxide for a minimum of 60 minutes at 20-25ºC (68-77ºF).

PERI-GUARD and SUPPLE PERI-GUARD are terminally sterilized using gamma irradiation and packaged within a sterile double-pouch system. The contents of the unopened, undamaged outer pouch are sterile.

PERI-GUARD and SUPPLE PERI-GUARD are MR Safe.

PERI-GUARD and SUPPLE PERI-GUARD utilize animal tissue; patient must be informed prior to any procedure.

See **Table 1** for PERI-GUARD and SUPPLE PERI-GUARD product models and sizes.

Table 1 – PERI-GUARD and SUPPLE PERI-GUARD Product Models and Sizes

PERI-GUARD Model Number	Size (cm)
PG0404	4 x 4
PG0608	6 x 8
PG0814	8 x 14
PG1016	10 x 16
PG1225	12 x 25
SUPPLE PERI-GUARD Model Number	**Size (cm)**
SPG0404	4 x 4
SPG0406	4 x 6
SPG0608	6 x 8
SPG0814	8 x 14
SPG1016	10 x 16

V. INTENDED USE/INDICATIONS FOR USE

Statement of Intended Use:

PERI-GUARD and SUPPLE PERI-GUARD are intended to be used as a surgical mesh.

Indications for Use:

PERI-GUARD is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, scrotal, and umbilical hernias).

SUPPLE PERI-GUARD is intended for use as a prosthesis for soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric

banding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, scrotal, and umbilical hernias).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

PERI-GUARD and SUPPLE PERI-GUARD are substantially equivalent to the predicate PERI-GUARD and SUPPLE PERI-GUARD devices based on having the same fundamental technology and intended use. The changes between the subject and predicate device include a change in sterilization method and re-designed packaging. The safety and performance of the subject devices has been evaluated through non-clinical testing.

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

- Intended Use
- Patch material
- Viral inactivation processing steps
- Strength, chemical and physical specifications

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

- Modified sterilization method from chemical sterilization to gamma irradiation
- Modified packaging from a jar to a double foil pouch

VII. PERFORMANCE DATA

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

- Visual
- Suture retention
- Dimensional
- Burst strength
- Collagenase digestion
- Denaturation Temperature
- Water Permeability
- Pliability
- Chemical and heavy metal residuals
- Bioburden
- Pyrogenicity/Endotoxins
- Temperature Excursion Testing
- Biocompatibility Assessment

The results of performance testing demonstrate that the modified PERI-GUARD and SUPPLE PERI-GUARD devices are substantially equivalent to the predicate devices.

Animal Studies

Two animal studies were performed to support the substantial equivalence of the chemically sterilized and gamma irradiated PERI-GUARD and SUPPLE PERI-GUARD devices.

Test	Results	Conclusions
Implantation: Porcine incisional hernia repair model for 6 months per ISO 10993-6	No test material-related changes among clinical observations, bodyweights, veterinary physicals, clinical pathology parameters, mortality, significant macroscopic or microscopic differences, tensile or burst strength, or clinical performance between the subject and predicate devices at Day 113±3 or Day 203±3.	The subject and predicate devices performed equivalently and had an equivalent safety profile in the *in vivo* porcine model for incisional hernia repair.
3-week Rat Calcification Potential Study	No significant mineralization was noted microscopically for either the subject or predicate device.	No significant difference in calcification potential.

Biocompatibility

The results of biocompatibility testing demonstrate the biocompatibility of the product in accordance with ISO 10993-1:2018 requirements for a permanent (long term) implant with tissue, bone or (non-direct) blood contact. As per FDA Guidance, testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, pyrogenicity, genotoxicity, implantation, hemolysis, and subchronic toxicity endpoints.

Shelf Life

Synovis has performed aging testing to support a 1 year shelf life claim.

Sterilization and Packaging

Sterilization validation was conducted according to ISO 11137 parts 1 and 2.

The modified packaging was designed and evaluated in accordance with ISO 11607-1. The integrity of the sterile barrier is supported by testing conducted in accordance with ASTM F88-15 and ASTM F2096-11.

Validation Studies

Human factors testing was conducted to confirm that the re-designed packaging allows for aseptic transfer of the product to the sterile field without compromising sterility, and that the modified packaging design does not impact the surface of the tissue patch.

VIII. CONCLUSION

The subject PERI-GUARD and SUPPLE PERI-GUARD devices share the same intended use and technological characteristics as the predicate devices. The physical, functional and performance specifications for the devices are substantially equivalent. Testing supports that the subject devices are as safe and effective as the predicate devices when used according to their labeling.