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

Re: K221032
Trade/Device Name: Vascu-Guard Vascular Repair Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene
Regulatory Class: Class II
Product Code: PSQ
Dated: September 20, 2022
Received: September 20, 2022

Dear Sajjad Megan:

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,

for Rachel Neubrander, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K221032

Device Name
VASCU-GUARD Vascular Repair Patch

Indications for Use *(Describe)*
VASCU-GUARD Vascular Repair Patch is used in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda and tibial vessels and arteriovenous access revisions.

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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"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: VASCU-GUARD Vascular Repair Patch
K221032

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: October 18, 2022

II. DEVICE

Device Trade Name: VASCU-GUARD

Common Name: Vascular Repair Patch

Classification Name: 21 CFR 870.3470 - Intracardiac Patch Or Pledget, Biologically Derived

Product Code: PSQ

III. PREDICATE DEVICES

Primary: VASCU-GUARD Peripheral Vascular Patch, K142461
Manufacturer: Synovis Life Technologies, Inc. (A Subsidiary of Baxter International Inc.)

Secondary: VASCU-GUARD Peripheral Vascular Patch, K983602
Manufacturer: Synovis Life Technologies, Inc. (A Subsidiary of Baxter International Inc.)

Additionally, Synovis PERI-STRIPS DRY Staple Line Reinforcement with VERITAS Collagen Matrix with SECURE GRIP Technology (K192615) serves as a Reference device for this 510k.

IV. DEVICE DESCRIPTION

VASCU-GUARD Vascular Repair Patch (VASCU-GUARD) is 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 20-25º (68-77ºF).

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

VASCU-GUARD is MR Safe.

VASCU-GUARD utilizes animal tissue; patient must be informed prior to any procedure.

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

Table 1 – VASCU-GUARD Product Models and Sizes

VASCU-GUARD Model Number	Size (cm)
VG0106	1 x 6
VG0108	0.8 x 8
VG0110	1 x 10
VG0209	2 x 9
VG0114	1 x 14
VG01510	1.5 x 10
VG02515	2.5 x 15

V. INTENDED USE/INDICATIONS FOR USE

Statement of Intended Use:

VASCU-GUARD is intended to be used as an intracardiac patch.

Indications for Use

VASCU-GUARD Vascular Repair Patch is used in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda and tibial vessels and arteriovenous access revisions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

VASCU-GUARD Vascular Repair Patch is substantially equivalent to the predicate VASCU-GUARD devices based on having the same fundamental technology and intended use. The changes between the subject and predicate devices include packaging and sterilization changes and new product sizes. The safety and performance of VASCU-GUARD Vascular Repair Patch has been evaluated through non-clinical testing.

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

- Intended Use (both predicates)

- Indication for use (primary predicate)
- Viral inactivation processing steps (both predicates)
- Sterilization method (primary predicate)
- Strength specifications (both predicates)
- Chemical and physical specifications (secondary predicate)

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

- Modified packaging design
- Same sterilization method but modified sterilization parameters and packaging for sterilization compared to the primary predicate
- New product sizes

VII. PERFORMANCE DATA

The following 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 the modified VASCU-GUARD device is substantially equivalent to the predicate VASCU-GUARD devices.

Biocompatibility

The results of new biocompatibility testing, along with applicable historical testing of the primary predicate device, demonstrate the biocompatibility of the product in accordance with ISO 10993-1 requirements for a permanent long-term implant with tissue/blood contact and equivalence to the predicate devices.

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 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 VASCU-GUARD device shares the same intended use and technological characteristics as the predicate VASCU-GUARD devices. The physical, functional and performance specifications for the devices are substantially equivalent. Testing supports that the subject device is as safe and effective as the predicate devices when used according to its labeling.