



Food and Drug Administration  
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Silver Spring, MD 20993-0002

November 25, 2014

Synovis Life Technologies, Inc.  
Jodi Jorgenson  
Manager, Regulatory Affairs  
2575 University Ave W.  
St. Paul, MN 55129

Re: K142461

Trade/Device Name: VASCU-GUARD Peripheral Vascular 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: DXZ  
Dated: August 28, 2014  
Received: September 02, 2014

Dear Ms. Jorgenson:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K142461

Device Name

VASCU-GUARD Peripheral Vascular Patch

Indications for Use (Describe)

VASCU-GUARD is intended for use in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda, and tibial blood 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 5.0 510(K) SUMMARY

**Applicant:**

Synovis Life Technologies, Inc.  
(a subsidiary of Baxter International Inc.)  
2575 University Avenue West  
St. Paul, MN 55114-1024  
Tel: 651-796-7300  
Fax: 651-642-9018

**Contact Person:**

Jodi Jorgenson  
Manager, Regulatory Affairs  
At address above

**Date Prepared:**

August 28, 2014

**Device Trade Name:**

VASCU-GUARD Peripheral Vascular Patch

**Common Name:**

Intracardiac patch

**Classification Name:**

Intracardiac patch or pledget  
21 CFR 870.3470  
Product Code: DXZ

**Predicate Devices:**

Synovis Life Technologies, VASCU-GUARD Peripheral Vascular Patch: K983602

**Device Description:**

VASCU-GUARD is prepared from bovine pericardium which is cross-linked with glutaraldehyde. VASCU-GUARD has been treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25°C. VASCU-GUARD is terminally sterilized using gamma irradiation.

VASCU-GUARD is packaged between two pieces of foam within a double sterile barrier pouch system. The contents of the unopened, undamaged package are sterile.

**Statement of Intended Use:**

VASCU-GUARD is intended for use in peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda and tibial blood vessels and arteriovenous access revisions.

**Summary/Comparison of Technological Characteristics:**

VASCU-GUARD Peripheral Vascular Patch is acting as its own predicate and is therefore substantially equivalent, having the same technological characteristics and intended use with the exception of the packaging and method of sterilization, which is the subject of this premarket notification submission.

The safety and performance of VASCU-GUARD Peripheral Vascular Patch was evaluated through non-clinical testing.

The bench and pre-clinical testing assessed the following aspects of the device:

- Suture retention
- Thickness
- Burst strength
- Tensile strength
- Collagenase digestion
- Chemical residuals
- Pyrogenicity/ LAL
- Sterilization validation
- Packaging and shelf-life
- Biocompatibility
- Animal studies

Bench testing results support the performance requirements for VASCU-GUARD Peripheral Vascular Patch. Biocompatibility testing was performed in accordance to ISO 10993-1:2009 (Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process). Various animal studies were conducted to support the safety and efficacy of VASCU-GUARD Peripheral Vascular Patch. The bench and preclinical studies indicate that the device is biocompatible and is substantially equivalent to the referenced predicate device.

**Conclusions:**

The safety and performance of VASCU-GUARD Peripheral Vascular Patch was evaluated through biocompatibility, bench testing and animal studies. VASCU-GUARD Peripheral Vascular Patch is substantially equivalent to the predicate device.