JAN 12 2005

K041736

510(k) Summary

General Information

Classification	Class II
Trade Name	PFA Vascular Patch
Submitter	Peritec Biosciences LTD 3291 Bremerton Road Cleveland, OH 44124 Tel: 216-595-9178
Contact	Robert M. Dickson President & CEO

Intended Use

The PFA patch is designed for use in peripheral arteries as a patch following arterial endarterectomy and as a tissue pledget for arterial surgery. It also can be used as a buttress for over sewing suture lines.

Predicate Devices

K942010 Vascu-Guard Peripheral Vascular Patch from Bio-Vascular, Inc.

Device Description

The PFA Vascular Patch is a cross-linked piece of bovine peritoneal / fascia tissue and is available in the following sizes:

0.8 cm x 3.0 cm
1.0 cm x 8.0 cm
2.0 cm x 9.0 cm

The device is packaged in an industry standard polymeric vial with a threaded cap sealed by a plastic shrink wrap. The tissue is packaged with a solution of glutaraldehyde. The sealed container is placed in a shelf

carton with the Instructions for Use. The shelf carton contains a freeze warning indicator. The product is provided sterile and is intended for single use only. It is not intended to be resterilized or reused.

Materials

All materials used in the manufacture of the PFA Vascular Patch are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included mechanical strength testing for the following parameters: failure tension, stiffness, relax slope, suture pull out strength, extensibility, fatigue tension, and creep tests.

In vivo animal testing comparing the bovine PFA patch to a commercially available arterial patch was conducted. PFA patches and control patches were implanted in canines. All vessels examined were patent with no evidence of stenosis. There was no evidence of aneurysm formation in any vessel and no difference between groups in inflammatory reaction. There was no neointimal hyperplasia or scarring in animals that received the PFA.

Summary of Substantial Equivalence

The PFA Vascular Patch is equivalent to the predicate products. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2005

PeriTec Biosciences, Ltd.
c/o Mr. Robert M. Dickson
CEO
3291 Bremerton Road
Pepper Pike, OH 44124

Re: K041736
PFA Patch – Vascular Patch (Cellular or Unwashed Version)
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: 74 DXZ
Dated: December 12, 2004
Received: December 20, 2004

Dear Mr. Dickson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochner

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): K041736

Device Name: PFA Patch – Vascular Patch

Indications For Use: The PFA Patch is intended for peripheral vascular reconstruction of blood vessels and arteriovenous (A/V) revisions.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041736