FEB 22 2000

K992537

Bio-Vascular, Inc.

510(k) Summary of Safety and Effectiveness

Applicant Name and Address: Bio-Vascular, Inc.
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Saint Paul, Minnesota 55114 USA

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Date Prepared: February 18, 2000

Trade & Common Names: Peri-Strips® – Sleeve, Peri-Strips® – Strip and Peri-Strips Dry™ (non-NaOH-treated); Peri-Strips® – Sleeve and Peri-Strips® – Strip and Peri-Strips Dry™ (NaOH-treated)

Device Classification Name: mesh, surgical, polymeric

Substantial Equivalence:

- Peri-Strips® – Sleeve (K983162), Peri-Strips® – Strip (K983162) and Peri-Strips Dry™ (K971048) [non-NaOH-treated];
- Peri-Strips® – Sleeve (K983162), Peri-Strips® – Strip (K983162) and Peri-Strips Dry™ (K983162) [NaOH-treated];

Device Descriptions:
Peri-Strips (sleeve and strip) and Peri-Strips Dry are surgical mesh patches derived from bovine pericardium that is cross-linked with glutaraldehyde.

Peri-Strips comes in two configurations: Peri-Strips-sleeve and Peri-Strips-strip. Each unit of Peri-Strips-sleeve is composed of two strips of bovine pericardial tissue. After the final manufacturing step, each strip of pericardium is sewn to a polyolefin strip with polypropylene suture to create a tubular sleeve. The tubular configuration facilitates usage of the product with surgical staplers. The polyolefin strip and sutures are removed after the Peri-Strips-sleeve is secured in place. Peri-Strips-strip is a flat piece of bovine pericardium that is sutured to the stapler by the surgical team.

For Peri-Strips Dry (PSD), the bovine pericardial patch is manufactured in the form of a strip and undergoes an additional manufacturing step of dehydration by vacuum drying. The strip is affixed to the surgical stapler with the aid of a hydrogel (PSD Gel) supplied with the product.

Product may be treated with 1 molar sodium hydroxide (1M NaOH) for 60-75 minutes at 20-25°C, rinsed with deionized (DI) water, and neutralized with citrate solution, followed by a final DI water rinse. Bio-Vascular believes that product subjected to the NaOH treatment performs in a substantially

equivalent manner to non-NaOH-treated product, and that there is no difference in safety and efficacy between treated and non-treated tissue.

Statement of Intended Use:
The indications for Peri-Strips (sleeve and strip) and Peri-Strips Dry are being expanded to include reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.

Summary/Comparison of Technological Characteristics:
These products are the same as the predicate devices except for the added indication of bariatric surgery.

The devices are comprised of bovine pericardium crosslinked with glutaraldehyde. They have an extensive clinical history of safe and effective use when used as surgical patches. Bench testing and animal testing show no difference in safety and efficacy between NaOH-treated and non-NaOH-treated tissue. Specifications of r NaOH-treated and non-NaOH-treated tissue are identical.

Safety and Effectiveness Conclusions:
These devices are substantially equivalent to the predicate devices with regard to safety and efficacy. No new questions of safety and efficacy are raised by the addition of the bariatric sugery indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2000

Ms. Mary Kay Kessinger Sobcinski, RN, MHA
Manager of Clinical Affairs
Bio-Vascular, Inc.
2575 University Avenue, Suite 180
Saint Paul, Minnesota 55114

Re: K992537
Trade Name: Peri-Strips® – Sleeve
Peri-Strips® - Strip
Peri-Strips® - Dry
Regulatory Class: II
Product Code: FTM
Dated: November 23, 1999
Received: November 24, 1999

Dear Ms. Kessinger Sobcinski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): [redacted] k992537

Device Name: Peri-Strips Dry® Staple Line Reinforcement (NaOH-treated product)

Indications for Use:
Peri-Strips Dry is intended to reinforce staple lines during lung and bronchus resections including: pneumonectomy, pneumoreduction, pneumectomy, segmentectomies, (segmental resections), wedge resections, blebectomies, lobectomies, bullectomies, bronchial resections and other lung incisions and excisions of lung and bronchus. **It can also be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
Per 21 CFR 801.109

OR

Over-The-Counter Use____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number k992537

Indications for Use

510(k) Number (if known): [redacted] K992587

Device Name: Peri-Strips Dry® Staple Line Reinforcement (non-NaOH-treated product)

Indications for Use:
Peri-Strips Dry is intended to reinforce staple lines during lung and bronchus resections including: pneumonectomy, pneumoreduction, pneumectomy, segmentectomies, (segmental resections), wedge resections, blebectomies, lobectomies, bullectomies, bronchial resections and other lung incisions and excisions of lung and bronchus. **It can also be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992537

Indications for Use

510(k) Number (if known): [redacted] K992537

Device Name: Peri-Strips® Staple Line Reinforcement – Strip Configuration (NaOH-treated product)

Indications for Use:
Peri-Strips is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. Peri-Strips can be used to reinforce staple lines during lung resections including pneumonectomy, pneumoreduction, pneumectomy, lobectomies, segmentectomies (segmental resections), wedge resections, bullectomies, blebectomies, bronchial resections, and other lung incisions and excisions of lung and bronchus. **It can also be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.** Other soft tissue deficiencies amenable to repair with Peri-Strips include defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias). Peri-Strips may be used with anastomotic staplers (when tissue division is desired) or with non-anastomotic staplers (when no tissue division is desired) according to the above indications.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
Per 21 CFR 801.109

OR

Over-The-Counter Use____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992537

Indications for Use

510(k) Number (if known): [redacted] K992537

Device Name: Peri-Strips® Staple Line Reinforcement – Strip Configuration (non-NaOH-treated product)

Indications for Use:
Peri-Strips is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. Peri-Strips can be used to reinforce staple lines during lung resections including pneumonectomy, pneumoreduction, pneumectomy, lobectomies, segmentectomies (segmental resections), wedge resections, bullectomies, blebectomies, bronchial resections, and other lung incisions and excisions of lung and bronchus. **It can also be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.** Other soft tissue deficiencies amenable to repair with Peri-Strips include defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias). Peri-Strips may be used with anastomotic staplers (when tissue division is desired) or with non-anastomotic staplers (when no tissue division is desired) according to the above indications.

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Prescription Use ✓ OR Over-The-Counter Use____
Per 21 CFR 801.109

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992537

Indications for Use K992537

510(k) Number (if known): [redacted]

Device Name: Peri-Strips® Staple Line Reinforcement – Sleeve Configuration (non-NaOH-treated product)

Indications for Use:
Peri-Strips is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. Peri-Strips can be used to reinforce staple lines during lung resections including pneumonectomy, pneumoreduction, pneumectomy, lobectomies, segmentectomies (segmental resections), wedge resections, bullectomies, blebectomies, bronchial resections, and other lung incisions and excisions of lung and bronchus. **It can also be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.** Other soft tissue deficiencies amenable to repair with Peri-Strips include defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias). Peri-Strips may be used with anastomotic staplers (when tissue division is desired) or with non-anastomotic staplers (when no tissue division is desired) according to the above indications.

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992537

Indications for Use K992537

510(k) Number (if known): [redacted]

Device Name: Peri-Strips® Staple Line Reinforcement – Sleeve Configuration (NaOH-treated product)

Indications for Use:
Peri-Strips is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers. Peri-Strips can be used to reinforce staple lines during lung resections including pneumonectomy, pneumoreduction, pneumectomy, lobectomies, segmentectomies (segmental resections), wedge resections, bullectomies, blebectomies, bronchial resections, and other lung incisions and excisions of lung and bronchus. **It can also be used for the reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.** Other soft tissue deficiencies amenable to repair with Peri-Strips include defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias). Peri-Strips may be used with anastomotic staplers (when tissue division is desired) or with non-anastomotic staplers (when no tissue division is desired) according to the above indications.

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