510(k) SUMMARY

Submitted by: Synovis Surgical Innovations
A Division of Synovis Life Technologies, Inc.
2575 University Ave. W.
St. Paul, MN 55114
Tel: 651-603-3700
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Contact Person: Angela Mallery
At address above

Device Trade Name: Peri-Strips® Staple Line Reinforcement - Sleeve Configuration
Peri-Strips® Staple Line Reinforcement - Strip Configuration
Peri-Strips® Dry Staple Line Reinforcement

Common Name: Surgical Mesh

Classification Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene

Predicate device: Peri-Strips® Staple Line Reinforcement (Synovis Surgical Innovations, a division of Synovis Life Technologies, Inc.) K983162
CV Peri-Guard Cardiovascular Patch (Synovis Surgical Innovations, a division of Synovis Life Technologies, Inc.) K983602

Device Description: An implantable surgical patch comprised of crosslinked bovine pericardium
Statement of Intended use:

Peri-Strips Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

Peri-Strips can be used for reinforcement of staple lines during lung and bronchus resections and during bariatric surgical procedures.

Peri-Strips can be used for reinforcement of staple lines during gastric, small bowel, mesentery, colon, and colorectal procedures.

Peri-Strips is intended to be used for reinforcement of suture-lines and staple-lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Technological Comparisons:

Peri-Strips® Staple Line Reinforcement is substantially equivalent to the predicate device, having the same technological characteristics.

Testing:

Peri-Strips® Staple Line Reinforcement is substantially equivalent to the predicate device in term of testing and indications for use.
Synovis Surgical Innovations  
c/o Ms. Angela Mallery  
Regulatory Affairs Manager  
2575 university Avenue W.  
St. Paul, MN  55114-1024

Re:  K040415  
Peri-Strips Staple Line Reinforcement  
Regulation Number:  21 CFR 870.3470  
Regulation Name:  Intracardiac Patch or Pledge  
Regulatory Class:  Class II (two)  
Product Code:  DXZ  
Dated:  February 20, 2004  
Received:  February 18, 2004

Dear Ms. Mallery:

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 (301) 594-4646. 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 Part 807.97) you may obtain. Other general information on your
responsibilities under the Act may be obtained 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,

Brain 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): K040415

Device Name: Peri-Strips Staple Line Reinforcement

Indications For Use:

Peri-Strips Staple Line Reinforcement is intended for use as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers when staple line reinforcement is needed.

Peri-Strips can be used for reinforcement of staple lines during lung and bronchus resections and during bariatric surgical procedures.

Peri-Strips can be used for reinforcement of staple lines during gastric, small bowel, mesentery, colon, and colorectal procedures.

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Prescription Use X AND/OR Over-The-Counter Use

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K040415