3.0 510(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 Fax: 651-603-5211
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	Mesh, Surgical 878.3300
Predicate device	Peri-Strips® Staple Line Reinforcement (Synovis Surgical Innovations, a division of Synovis Life Technologies, Inc.) - K983162 SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material (W.L. Gore & Associates, Inc., Flagstaff, AZ) K032865
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 also be used for reinforcement of staple lines during gastric, small bowel, mesentery, colon, and colorectal procedures.
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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2004

Ms. Angela Mallery
Regulatory Affairs Manager
Synovis Life Technologies, Inc.
2575 University Avenue W.
St. Paul, Minnesota 55114

Re: K040119
Trade/Device Name: Peri-Strips Staple Line Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: January 16, 2004
Received: January 20, 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) 594-4659. 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,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040119

Indications for Use

510(k) Number (if known): K040119

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 also be used for reinforcement of staple lines during gastric, small bowel, mesentery, colon, and colorectal procedures.

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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040119