510(k) SUMMARY 1/2

Submitted by:	Synovis Surgical Innovations 2575 University Ave. W. St. Paul, MN 55114-1024 Tel: (651) 796-7300 Fax: (651) 642-9018
Contact Person:	James Jenkins Tel: (651) 796-7368 Fax: (651) 796-7468
Device Trade Name:	To Be Determined
Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical 878.3300
Predicate devices:	Veritas® Collagen Matrix, K030879 Synovis Surgical Innovations Peri-Strips Dry (PSD), K040415 Synovis Surgical Innovations
Device Description:	Veritas Dry is intended to be used as a staple line buttress. Veritas Dry is composed of dehydrated non-crosslinked bovine pericardium, to facilitate easy loading of the pericardium strips onto the stapler forks, an anvil and a cartridge strip are secured in a mounting unit. One mounting unit is used for each stapler firing. Each Veritas Dry unit is provided sterile in a double pouch.
Statement of Intended use:	Veritas Dry 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. Veritas Dry can be used for reinforcement of staple lines during lung and bronchus resections and during bariatric surgical procedures. Veritas Dry can be used for reinforcement of staple lines during gastric, small bowel, mesentery, colon, and colorectal procedures. Veritas Dry is intended to be used for reinforcement of suture-lines and staple-lines (for example: occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Technological Comparisons:	Veritas Dry is substantially equivalent to the predicate devices, having equivalent technological characteristics and indications for use.
Testing:	Veritas Dry is substantially equivalent to the predicate devices in terms of physical characteristics and test results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

Mr. James Jenkins
Regulatory Specialist
Synovis Surgical Innovations
2575 University Avenue West
St. Paul, Minnesota 55114

Re: K041669
Trade/Device Name: Veritas Dry Collagen Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: September 10, 2004
Received: September 14, 2004

Dear Mr. Jenkins:

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) 276-0115. 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,

for Miriam C. Provost

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

Indications for Use

510(k) Number (if known): K041669

Device Name: Veritas Dry Collagen Matrix

Indications For Use:

Veritas Dry 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.

Veritas Dry can be used for reinforcement of staple lines during lung and bronchus resections and during bariatric surgical procedures.

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

Veritas Dry is intended to be used for reinforcement of suture-lines and staple-lines (for example: occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

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)

Miriam C. Provost

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K041669