2.0 510(K) SUMMARY

K083039

Submitted by

Synovis Surgical Innovations
2575 University Avenue West
St. Paul, MN 55114-1024
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NOV 2 6 2008

Contact Person

Jodi Jorgenson
At address above

Date Prepared October 13, 2008

Device Trade Name: Veritas® Collagen Matrix (Dry)
Marketed as Peri-Strips Dry® with Veritas® Collagen Matrix.

Common Name Surgical Mesh

Classification Name Mesh, Surgical
21 CFR 878.3300
Product Code: FTM

Predicate devices Veritas® Collagen Matrix (Dry) K041669 and Veritas® Collagen Matrix (Wet) K062915
(Device acting as its own predicate.)

Device Description Veritas Collagen Matrix is an implantable surgical mesh comprised of non-crosslinked bovine pericardium. Veritas Collagen Matrix bovine pericardium is procured in the United States from cattle less than 30 months of age.

Veritas Collagen Matrix allows for neo-collagen formation and neo-vascularization of the implanted device and permits replacement of the device with host tissue, or remodeling. Veritas Collagen Matrix also minimizes tissue attachment to the device in case of direct contact with viscera.

Veritas Collagen Matrix (Dry) is used for buttressing and reinforcing surgical staple lines and is currently available in configurations for multiple sizes and brands of both linear and circular staplers.

Statement of Intended use

Intended Use (Unchanged from previous clearances)

The device is intended to be used as a staple line buttress

Indications for Use (Unchanged from previous clearances)

Veritas Collagen Matrix (Dry) 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 Collagen Matrix (Dry) can be used for reinforcement of staple lines during lung and bronchus resection, during gastric, bariatric, small bowel, mesentery, colon and colorectal procedures, and cardiac surgery (for example: occlusion of the left atrial appendage during open chest procedures).

Veritas Collagen Matrix (Dry) minimizes tissue attachment to the device in case of direct contact with viscera.

Technological Comparisons

Veritas Collagen Matrix (Dry) is acting as its own predicate and is therefore substantially equivalent, having the same technological characteristics and intended use with the exception of the method of attachment of the buttress to the stapler, which is the subject of this submission.

Technology/Device Testing

Veritas Collagen Matrix (Dry) is unchanged and previous testing applies. The testing presented in this submission is specifically related to the use of an adhesive, which is the new method for attachment of the buttress to the stapler. The testing focuses on the biocompatibility of the adhesive and its ability to allow the device to function as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Synovis Surgical Innovations
% Ms. Jodi Jorgenson
Sr. Regulatory Affairs Specialist
2575 University Avenue West
St. Paul, Minnesota 55114-1024

NOV 2 6 2008

Re: K083039
Trade/Device Name: Veritas Collagen Matrix (Dry)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: October 13, 2008
Received: October 14, 2008

Dear Ms. Jorgenson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K083039

Device Name: Veritas Collagen Matrix (Dry)

Indications For Use:

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Veritas Collagen Matrix (Dry) can be used for reinforcement of staple lines during lung and bronchus resection, during gastric, bariatric, small bowel, mesentery, colon and colorectal procedures, and cardiac surgery (for example, occlusion of the left atrial appendage during open chest procedures.

Veritas Collagen Matrix (Dry) minimizes tissue attachment to the device in case of direct contact with viscera.

Mark N Milliken

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

510(k) Number K083039

Prescription Use X 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)