

**3.0 SUMMARY OF SAFETY AND EFFECTIVENESS**

**Submitted by** Synovis Surgical Innovations **DEC - 6 2006**  
 2575 University Ave. W.  
 St. Paul, MN 55114  
 Tel: 651-796-7300  
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**Contact Person** Cynthia Lamarucciola  
 At address above

**Device Trade Name:** Veritas® Collagen Matrix

**Common Name** Surgical Mesh

**Classification Name** Mesh, Surgical  
 878.3300

**Predicate devices** Veritas® Collagen Matrix K002233, K030879 and K040119  
 Synovis Surgical Innovations (Acting as its own predicate.)

PARIETEX® COMPOSITE Mesh, K002699, K040998, K050187  
 MacroPore Surgi-Wrap MAST Bioresorbable Sheet, K031955  
 GORE-TEX® Dualmesh® Biomaterial, K992189  
 Genzyme Serpramesh™ IP, K040868

**Device Description** An implantable surgical patch comprised of non-crosslinked bovine pericardium. Veritas® Collagen Matrix undergoes proprietary processing that allows neo-collagen formation and neo-vascularization of the implanted device and permits replacement of the device with host tissue, or remodeling.

<b>Statement of Intended use</b>	<p>Veritas Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following:</p> <p>Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus.</p> <p>Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.</p> <p>Abdominal and thoracic wall repair, muscle flap reinforcement, rectal and vaginal prolapse repair, urinary incontinence treatment, reconstruction of the pelvic floor, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).</p> <p><i>Veritas Collagen Matrix minimizes tissue attachment to the device in case of direct contact with viscera.</i></p>
<b>Technological Comparisons</b>	<p>Veritas Collagen Matrix is acting as its own predicate and is therefore substantially equivalent, having the same technological characteristics and intended use with the exception of the additional intended use, which is the subject of this submission.</p>
<b>Technology/Device Testing</b>	<p>Veritas Collagen Matrix is acting as its own predicate and is therefore substantially equivalent in terms of testing.</p>
<b>Indication Testing</b>	<p>An animal study was conducted, specific to the subject of this submission. The study concluded that Veritas® Collagen Matrix demonstrates minimal tissue attachment to the viscera when compared to a named predicate.</p>



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Synovis Surgical Innovations  
% Ms. Cynthia Lamarucciola  
Regulatory Affairs Manager  
2575 University Avenue, West  
St. Paul, Minnesota 55114-1024

May 2, 2013

Re: K062915  
Trade/Device Name: Veritas<sup>®</sup> Collagen Matrix  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: Class II  
Product Code: FTM, OXE, OXB, PAJ  
Dated: October 31, 2006  
Received: November 2, 2006

Dear Ms. Lamarucciola:

This letter corrects our substantially equivalent letter of December 6, 2006.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, FOR

**Peter D. Rumm -S**

Mark Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K062915

Device Name: Veritas Collagen Matrix

### Indications For Use:

Veritas Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies; this includes but is not limited to the following:

Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incision and excision of the lung and bronchus.

Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.

Abdominal and thoracic wall repair, muscle flap reinforcement, rectal prolapse excluding rectocele, reconstruction of the pelvic floor excluding transvaginal organ prolapse repair, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

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

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

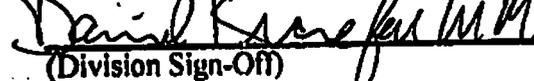
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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510(k) Number   K062915