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JAN 11 2012

510(K) SUMMARY

1 Submitter Information

A.	Company Name:	Synovis Orthopedic and Woundcare, Inc.
B.	Company Address:	6 Jenner, Suite 150 Irvine, CA 92618
C.	Company Phone:	(949) 502-3240
D.	Company Facsimile:	(949) 502-3241
E.	Contact Person:	Amy Boucly Manager, Regulatory Affairs/Quality Assurance
F.	Date:	01/04/12

2 Device Identification

A.	Device Trade Name:	Synergy™ Tissue Matrix
B.	Common Name:	Surgical Mesh
C.	Classification Name(s):	Mesh, Surgical
D.	Classification Regulation:	878.3300
E.	Device Class:	Class II
F.	Device Code(s):	FTM
G.	Advisory Panel:	General and Plastic Surgery

3 Identification of Predicate Devices

Synergy Tissue Matrix is substantially equivalent to the following surgical mesh devices, which are cleared for commercial distribution in the United States:

- OrthADAPT® Bioimplant, Pegasus Biologics, Inc., K043388, K071065
- Veritas® Collagen Matrix, Synovis Surgical Innovations, K002233, K030879, K062915
- CuffPatch® Surgical Mesh, Organogenesis, Inc. K042809
- PROPatch® Soft Tissue Repair Matrix, CryoLife, Inc., K061892, K101587

4 Device Description

Synergy Tissue Matrix is an implantable biologic mesh comprised of non-crosslinked bovine pericardium. Synergy Tissue 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.

5 Statement of Intended Use

Synergy is intended to be used for implantation to reinforce soft tissue, including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, hernias, suture-line reinforcement and other reconstructive procedures.

The device is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

Synergy is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

6 Biocompatibility and Performance Data

Biocompatibility testing, biomechanical bench testing, characterization testing and *in vivo* performance testing have been conducted to evaluate the biological safety and biomechanical performance characteristics of Synergy.

Biocompatibility testing was performed in accordance with ISO 10993-1 (*Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process).* Other safety testing included a viral inactivation study, pyrogen testing and residual chemicals assessment. Results indicate that the device biocompatibility profile is acceptable and equivalent to the predicate devices.

Biomechanical testing, including tensile strength, burst strength and suture pull-out strength was performed and results indicate that the device is equivalent to the predicate devices and satisfies mechanical performance requirements for its intended use. Additionally, results of physical, chemical and structural characterization testing indicate that the device is comparable to predicate devices.

Animal implant studies were performed to confirm the functionality and tissue response characteristics of the Synergy Tissue Matrix. Results indicate a normal tissue healing response and confirm the subject device's remodeling capability.

7 Comparison with Predicate Devices

The Synergy Tissue Matrix is equivalent to Veritas and PROPatch with respect to materials, physical and performance characteristics and biological attributes. It is also substantially equivalent to the OrthADAPT, PROPatch and CuffPatch in indications for use and physical, chemical and biomechanical characteristics.

Indications for use do not include urinary incontinence, rectal or vaginal prolapse, or other pelvic floor surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Synovis Orthopaedic and Woundcare, Incorporated
% Ms. Amy Boucly
Manager, Regulatory Affairs/Quality Assurance
6 Jenner, Suite 150
Irvine, California 92618

JAN 11 2012

Re: K113460
Trade/Device Name: Synergy™ Tissue Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM
Dated: November 18, 2011
Received: November 22, 2011

Dear Ms. Boucly:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 18, 2011

Indications for Use

510(k) Number (if known): K113960

Device Name: Synergy™ Tissue Matrix

Indications For Use:

Synergy™ Tissue Matrix is intended to be used for implantation to reinforce soft tissue, including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, hernias, suture-line reinforcement and other reconstructive procedures.

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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