

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
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- E. Contact Person: Amy Boucly
Manager, Regulatory Affairs/Quality Assurance
- F. Date: 06/25/12

2 Device Identification

- A. Device Trade Name: OrthADAPT® Bioimplant
- B. Common Name: Surgical Mesh
- C. Classification Name(s): Surgical Mesh
- D. Classification Regulation: 21 CFR 878.3300
- E. Device Class: Class II
- F. Device Code(s): OWY, FTM
- G. Advisory Panel: General and Plastic Surgery

3 Identification of Predicate Devices

The OrthADAPT Bioimplant is substantially equivalent to the Fortaflex Surgical Mesh manufactured by Organogenesis, Inc. (K020049), and Depuy Restore Orthobiologic Soft Tissue Implant, manufactured by Depuy Orthopedic, Inc. (K001738).

4 Device Description

The OrthADAPT Bioimplant is a decellularized equine pericardium. The OrthADAPT Bioimplant has been crosslinked and exposed to a liquid chemical sterilant. The product has passed the USP sterility test and satisfies FDA requirements for LAL endotoxin limit for a medical device. The product must be rinsed prior to use.

5 Indications for Use

The OrthADAPT® Bioimplant (Surgical Mesh) 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 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.

OrthADAPT® 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.

OrthADAPT® is intended for one-time use only.

6 Substantial Equivalence

The OrthADAPT is comparable to the predicate devices in terms of intended use, technology and performance: It is similar to the predicate devices in that it has the same intended use of soft tissue reinforcement, is a collagen mesh and is similar in design and materials. The results of biocompatibility and performance testing demonstrate that OrthADAPT is comparable to the predicate devices.



Pegasus Biologics, Incorporated
% Mr. Muir S. Meinhold
Director, Regulatory Affairs, Quality Assurance
10 Pasteur, Suite 150
Irvine, California 92618

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

AUG 27 2012

Re: K043388

Trade/Device Name: Pegasus Biologics[®] OrthADAPT[™] FX,PX,MX

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical Mesh

Regulatory Class: Class II

Product Code: FTM, OXB, OXE, OWY

Dated: June 17, 2005

Received: June 20, 2005

Dear Mr. Meinhold:

This letter corrects our substantially equivalent letter of August 5, 2005.

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 (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 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 Melkerson
Director
Division of Surgical, Orthopedics
and Restorative Devices
Office of Device Evaluation
Center for Device and
Radiological Health


Pete O. Downing
Dep + Carol D. R.

Enclosure

