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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:	06/25/12

2 Device Identification

A.	Device Trade Name:	OrthADAPT® PR Bioimplant
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):	FTL, FTM, OXA, OXD, OWX
G.	Advisory Panel:	General and Plastic Surgery

3 Identification of Predicate Devices

The OrthADAPT® PR Bioimplant 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
- Avaulta Plus® BioSynthetic Support System, C.R. Bard, Inc., K063712
- AMS Elevate® Prolapse Repair System, American Medical Systems (AMS) K080185
- PeriPatch™ Sheet, PM Devices, K040835
- SeriScaffold Surgical Mesh, Serica Technologies, Inc., K080442
- Surgicraft Surgical Mesh System, Surgicraft, K072370

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4 Device Description

OrthADAPT® PR is comprised of collagen matrix reinforced by a woven polymer to provide permanent durability. The collagen matrix, which is derived from the same equine pericardial tissue used in the fabrication of its predicate device, the OrthADAPT® Bioimplant, has been decellularized and crosslinked and the entire device has been exposed to a liquid chemical sterilant. The product passes USP sterility testing and satisfies FDA requirements for LAL endotoxin limit for a medical device. The product must be rinsed prior to use following the procedures described in the Instructions for Use.

5 Statement of Intended Use

OrthADAPT® PR 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.

OrthADAPT® PR 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, and *in vivo* performance testing have been conducted to evaluate the biological safety and biomechanical performance characteristics of OrthADAPT® PR. Biocompatibility test results indicate that the device biocompatibility profile is equivalent to the predicate devices. Biomechanical test results indicate that the device is equivalent to the predicate devices and satisfies mechanical performance requirements for its intended use. An animal implant study was performed to confirm the functionality and tissue response characteristics of the OrthADAPT® PR.

7 Comparison with Predicate Devices

The OrthADAPT® PR 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 comprised of similar materials (collagen and polymeric materials) and is similar in design. The results of testing demonstrate that the performance of OrthADAPT® PR is comparable to the predicate devices.

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

Pegasus Biologics, Incorporated
% Ms. Amy Boucly
Director, Regulatory Affairs
6 Jenner Street, Suite 150
Irvine, California 92618

AUG 29 2012

Re: K090288
Trade/Device Name: OrthADAPT® PR Bioimplant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class 2
Product Code: FTL, FTM, OXA, OXD, OWX
Dated: February 3, 2009
Received: February 5, 2009

Dear Ms. Boucly:

This letter corrects our substantially equivalent letter of May 5, 2009.

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,

For Mark N. Melkerson

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

Enclosure

INDICATIONS FOR USE

510(k) Number: K090288

Device Name: OrthADAPT® PR

Indications for Use: OrthADAPT® PR 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 _____
(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)

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

510(k) Number K090288