K112786

OCT 25 2011

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
F.	Date:	October 17, 2011

2 Device Identification

A.	Device Trade Name:	PROseries™ Bioimplants-PROcuff™/PROankle™
B.	Models:	PROcuff™, PROankle™, PROxxx (TBD)
C.	Common Name:	Surgical Mesh
D.	Classification Name(s):	Mesh, Surgical
E.	Classification Regulation:	878.3300
F.	Device Class:	Class II
G.	Device Code(s):	FTM, FTL
H.	Advisory Panel:	General and Plastic Surgery

3 Identification of Predicate Device

The PROseries™ Bioimplants – PROcuff™/PROankle™ are substantially equivalent to the OrthADAPT® PR Bioimplant, Pegasus Biologics, Inc., K090288.

4 Device Description

PROseries Bioimplants are comprised of collagen matrix reinforced by a woven polymer to provide permanent durability. The collagen matrix, derived from equine pericardial tissue, 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

PROseries™ Bioimplants are 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.

PROseries Bioimplants are 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 PROseries Bioimplants.

7 Comparison with Predicate Devices

The PROseries Bioimplants are identical to the predicate device in terms of design, technology, intended use, materials, performance and processing methods.

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 Orthopedic and Woundcare, Inc.
% Ms. Amy Boucly
Manager, Regulatory Affairs
6 Jenner Street, Suite 150
Irvine, California 92618

OCT 25 2011

Re: K112786
Trade/Device Name: PROseries Bioimplants – PROcuff™/PROankle™
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM, FTL
Dated: September 23, 2011
Received: September 27, 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

Indications for Use

510(k) Number (if known): K112786

Device Name: PROseries Bioimplants – PROcuff /PROankle

Indications For Use:

PROseries™ Bioimplants are 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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kwon for MSM

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

510(k) Number K112786