K071016
Page 1 of 2

7.0 510(k) SUMMARY

NAME OF SPONSOR: Depuy Orthopaedics, Incorporated
700 Orthopaedic Drive
Warsaw, Indiana 46581

510(k) CONTACT: Kathy Harris
Director of Regulatory Affairs

SEP - 4 2007

DATE: March 30, 2007

TRADE NAME: DePuy Restore Orthobiologic Soft Tissue Implant
COMMOM NAME: Surgical Mesh
CLASSIFICATION: 21 CFR §878.3300, Class II
PRODUCT CODE: FTM

SUBSTANTIALLY EQUIVALENT DEVICES:

- DePuy Restore Orthobiologic Soft Tissue Implant (K031969)
- CryoLife ProPatch Soft Tissue Repair Matrix (K061892)
- W.L. Gore Absorbable Mesh (K033671)

DEVICE DESCRIPTION AND INTENDED USE:
The DePuy Restore Orthobiologic Soft Tissue Implant is manufactured from porcine small intestinal submucosa (SIS), comprised predominantly of water and collagen, and will be supplied in a sheet or strand configuration in sterile form in a sealed double pouch system.

The DePuy Restore Orthobiologic Soft Tissue Implant is intended to reinforce soft tissue where weakness exists, specifically for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patella, Achilles, biceps, quadriceps, and other tendons. The device 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. The DePuy Restore Orthobiologic Soft Tissue Implant is also intended for use during general tissue reconstruction of the periosteum. The device reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The DePuy Restore Orthobiologic Soft Tissue Implant is substantially equivalent to the above listed devices (K031969, K061892, K033671) in that it is manufactured from the same material (SIS) as K031969, and has the same intended use and similar indications as K031969, K061892, and K033671, raising no new types of safety and effectiveness questions.

DISCUSSION OF TESTS AND TEST RESULTS:
The DePuy Restore Orthobiologic Soft Tissue Implant met the requirements of extensive biocompatibility testing, viral inactivation testing, and mechanical testing, demonstrating suitability for use.

page 2 of 2

CONCLUSIONS DRAWN FROM TESTS:
Outcomes from the evaluation of the DePuy Restore Orthobiologic Soft Tissue Implant provide evidence of its suitability for use in soft tissue repair and substantial equivalency to predicate devices in terms of intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc
% Ms. Kathy Harris
Director Regulatory Affairs
700 Orthopaedic Drive
PO Box 988
Warsaw, IN 46581-0988

SEP - 4 2007

Re: K071016
Trade/Device Name: DePuy Restore Orthobiologic Soft Tissue Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: August 10, 2007
Received: August 13, 2007

Dear Ms. Harris:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number (if known): K071016

Device Name: DePuy Restore Orthobiologic Soft Tissue Implant

Indications For Use:

The DePuy Restore Orthobiologic Soft Tissue Implant is intended to reinforce soft tissue where weakness exists, specifically for the reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery, including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, and other tendons. The device 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. The DePuy Restore Orthobiologic Soft Tissue Implant is also intended for use during general tissue reconstruction of the periosteum. The device reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071016