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SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF SPONSOR:
DePuy, Inc.
P.O. Box 988
Warsaw, Indiana 46581-0988

510(k) CONTACT:
Kathy K. Trier, Ph.D.
Senior Regulatory Associate

TRADE NAME:
DePuy Restore® Orthobiologic Soft Tissue Implant

COMMON NAME:
Surgical Mesh
CLASSIFICATION:
878.3300 – Surgical Mesh
DEVICE PRODUCT CODE:
79 FTM

SUBSTANTIALLY EQUIVALENT DEVICES:

- Restore® Orthobiologic Soft Tissue Implant (K982330)
- Restore® Orthobiologic Soft Tissue Implant (K001738)

DEVICE DESCRIPTION AND INTENDED USE:
The Restore® Orthobiologic Soft Tissue Implant is a round device, manufactured from 10 plys of Small Intestine Submucosa (SIS). SIS is a biomaterial derived from porcine small intestine. SIS is composed predominately of water and collagen. This material is identical to the material and device configuration approved in K982330 for use in general surgical procedures for reinforcement of soft tissue where weakness exists and K001738 for reinforcement of the soft tissues, which are repaired by suture or suture anchors during rotator cuff repair, limited to the supraspinatus.

This submission is for the following expanded intended use:

The DePuy Restore® Orthobiologic Soft Tissue Implant is intended for use for reinforcement of the soft tissues, which are repaired by suture or suture anchors, during rotator cuff repair surgery.

The Restore® implant is not intended to replace normal body structure or provide the full mechanical strength to repair the rotator cuff. Sutures to repair the tear and suture or bone anchors to reattach the tissue to the bone provide mechanical strength for the rotator cuff repair. The Restore® implant 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 device (K982330, K001738) in that it is manufactured from the same material (SIS, porcine small intestine submucosa), has the same device design, has the same general and specific use as the predicate device, and has the additional expanded indication for use

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that does not alter the therapeutic effect based upon safety and effectiveness considerations and evidenced by clinical data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2003

Dr. Kathy K. Trier, Ph.D.
Senior Regulatory Affairs Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K031969
Trade/Device Name: Restore® Orthobiologic Soft Tissue Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: June 24, 2003
Received: June 26, 2003

Dear Dr. Trier:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031969

510(k) Number (if known)

Device Name: Restore® Orthobiologic Soft Tissue Implant

Indications for Use:

The DePuy Restore® Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. In addition, the implant is intended for use in the specific application of reinforcement of the soft tissues, which are repaired by suture or suture anchors, during rotator cuff repair surgery.

The Restore® Implant is not intended to replace normal body structure or provide the full mechanical strength to repair the rotator cuff. Sutures to repair the tear and suture or bone anchors to reattach the tissue to the bone provide mechanical strength for the rotator cuff repair. The Restore® Implant reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.

Concurrence of CDRH, Office of Device Evaluation

Miriam C. Provost

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

510(k) Number K031969

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)