SEP 25 1998

K982330

SUMMARY OF SAFETY AND EFFECTIVENESS

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

510(k) CONTACT: Cheryl Hastings
Manager, Regulatory Submissions

TRADE NAME: DePuy OrthoTech Restore Orthobiologic Soft Tissue Implant

COMMON NAME: Surgical Mesh

CLASSIFICATION: 878.3300 – Surgical Mesh

DEVICE PRODUCT CODE: 79 FTM

SUBSTANTIALLY EQUIVALENT DEVICES:

- Organogenesis Graft Patch (K970561)
- Sentron SIS Hernia Repair Device (K974540)
- Bio-Vascular Supple Peri-guard (K923657)
- Cook Biotech Inc. SIS Wound Dressing (K973170)
- Cook Biotech Inc. SIS Surgical Mesh (K980431)

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 approved in IDE G960196 for investigational use as an Anterior Cruciate Ligament (ACL) replacement device and submitted in K974540 for Hernia Repair.

The Restore Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. The device is intended to act as a resorbable scaffold which initially has sufficient mechanical strength to assist with a soft tissue repair, but then resorbs and is replaced by the patients own tissue.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The DePuy OrthoTech Restore Orthobiologic Soft Tissue Implant is substantially equivalent to the above listed devices in that it is manufactured from the same material (SIS, porcine small intestine submucosa) as the Sentron SIS Hernia Repair Device and the Cook Biotech Inc. SIS Wound Dressing and SIS Surgical Mesh. The material is very similar to that of the Organogenesis Graft Patch (described as cross-linked porcine collagen). It has the same intended use (reinforcing soft tissue) as the Organogenesis Graft Patch, the Bio-Vascular Supple Peri-guard, and the SIS Surgical Mesh and it has a similar design to all five of these soft tissue patches. Mechanical testing shows that the Restore Orthobiologic Soft Tissue Implant and the BioVascular Supple Periguard have comparable suture retention strength and mechanical strength as measured by ball burst tests. Biocompatibility tests, performed according to ISO 10993, other accepted standards and other appropriate test methods indicate that the SIS material is biocompatible. Numerous animal efficacy studies indicate that SIS, in various configurations is efficacious when used for soft tissue repair or soft tissue replacement. These studies include: repair of abdominal aponeuroses and the

abdominal wall, fascial and capsular defects, and patellar and achilles tendons, and replacement of infraspinatus tendons and cranial cruciate ligaments. In all of these studies the SIS implant served as a scaffold for new tissue formation and no evidence of rejection of the material was observed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 1998

Ms. Cheryl K. Hastings
Manager, Regulatory Submission
Depuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K982330
Trade Name: DePuy OrthoTech Restore Orthobiologic Soft Tissue Implant
Regulatory Class: II
Product Code: FTM
Dated: June 30, 1998
Received: July 02, 1998

Dear Ms. Hastings:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

K982330

510(k) Number (if known)_____

Device Name DePuy OrthoTech Restore Orthobiologic Soft Tissue Implant

Indications for Use:

The DePuy OrthoTech Restore Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982330

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