K021056 (1 of 2)

# 510(k) SUMMARY

OCT 31 2002

## Tissue Science Laboratories, PLC's Permacol™ - Crosslinked Porcine Dermal Collagen Surgical Mesh

### Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Howard M. Holstein

Date Prepared: April 1, 2002

### Name of Device and Name/Address of Sponsor

Tissue Science Laboratories, PLC
7th Floor, Victoria House
Victoria Road
Aldershot
Hants GU11 1EJ
United Kingdom

### Common or Usual Name

Surgical Mesh

### Classification Name

Surgical Mesh

### Predicate Devices

DePuy, Inc.'s Restore® Orthobiologic Soft Tissue Implant (K001738) ("Restore®"), Organogenesis, Inc.'s Fortaflex Surgical Mesh (K011025) ("Fortaflex"); and Cook Biotech's SurgiSIS™ (K980431) ("SurgiSIS™").

## Intended Use

Permacol™ - Crosslinked Porcine Dermal Collagen Surgical Mesh ("Permacol™ ") is intended to be used for reinforcement of the soft tissues which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.

## Technological Characteristics and Substantial Equivalence

Permacol™ is substantially equivalent to its predicates because it has the same intended use and very similar technological characteristics. Permacol™ and its predicates are intended for use in a broad range of surgical procedures for soft tissue repair/reinforcement. Permacol™ and Restore® are specifically indicated for reinforcement of the soft tissues which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.

The technological characteristics of Permacol™ are very similar to its predicate devices. For example, Permacol™ is available in sheet form, like Fortaflex and SurgiSIS™. All of the devices also share similar dimensions, thickness, and composition. Finally, Permacol™ and Restore® present the same questions of safety and effectiveness with regard to mechanical strength and durability. Thus, Permacol™ is substantially equivalent to its predicate devices.

## Performance Data

Mechanical testing of Permacol™ has been performed in accordance with FDA's Surgical Mesh 510(k) Guidance. The results demonstrate that Permacol™ provides appropriate tensile strength, elasticity, stiffness, suture pullout strength, tear resistance, and puncturability, for use in soft tissue repair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2002

Tissue Science Laboratories, PLC
c/o Hogan & Hartson, L.L.P.
Howard M. Hostein, Esq.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K021056
Trade/Device Name: Permacol™ Crosslinked Porcine Dermal Collagen Surgical Mesh
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: August 20, 2002
Received: August 21, 2002

Dear Mr. Holstein:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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" (21 CFR Part 807.97). 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

# INDICATIONS FOR USE FORM

510(k) Number (if known): K021056

**Device Name:** Permacol™ - Crosslinked Porcine Dermal Collagen Surgical Mesh

**Indications for Use:** Permacol™ - Crosslinked Porcine Dermal Collagen Surgical Mesh is indicated for use in the reinforcement of the soft tissues which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021056