K013625

JAN 1 7 2002

510(k) Summary

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

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Submission Correspondent:

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Date Prepared: October 26, 2001

Name of Device and Name/Address of Sponsor

Permacol™ Crosslinked Porcine Dermal Collagen Surgical Mesh

Sponsor:

Tissue Sciences Laboratories PLC
7th Floor, Victoria House
Victoria Road
Aldershot
Hants GU11 1SJ
United Kingdom
Tel. (011) 44 125 233 3002
Fax (011) 44 125 233 3010

Common or Usual Name

Permacol™

Classification Name

Surgical Mesh

Predicate Devices

1. Tissue Science Laboratories, PLC's Permacol™ Crosslinked Porcine Dermal Collagen Mesh (K992556) ("Permacol")
2. Tissue Technologies, Inc.'s Soft Form Facial Implant (K002071, K000849, K973462) ("Soft Form")
3. Organogenesis, Inc.'s Fortaflex Surgical Mesh (K011025) ("Fortaflex")
4. S. Jackson, Inc.'s Sterile SupraFOIL Smooth Nylon Foil Sheets (K973379) ("SupraFOIL")

Intended Use

Permacol™ is indicated for use to provide soft tissue repair or reinforcement in plastic and reconstructive surgery of the face and head.

Technological Characteristics

Permacol™ consists of a sterile, tough, off-white, moist, flexible, fibrous flat sheet comprised of acellular crosslinked porcine dermal collagen and elastin. Each impermeable inner pack contains a small quantity of saline to maintain its moistness and flexibility. The product is available in thicknesses of 0.5-1.5 mm and dimensions of 0.8 x 0.8 to 4 x 6 inches.

To use Permacol™ for soft tissue repair, the surgeon first removes damaged or necrotic tissue. Permacol™ can be cut to the desired

size and shape required to reinforce or repair the tissue. It is flexible and can conform to the complex surface shapes of human anatomy. Once the product is cut to the desired dimensions, it can be sutured in position if desired. Permacol™ provides sufficient mechanical strength to secure sutures to the surrounding healthy tissue until healing occurs. Similar procedures are used with other surgical mesh devices.

Summary Basis for the Finding of Substantial Equivalence

Permacol™ has the same intended use and substantially the same indications for use as the predicates, which have previously been cleared for use in the face and in reconstructive procedures in the head. Furthermore, the technological features of Permacol™ are substantially similar to the predicates. Although there are minor differences between the products, *i.e.*, with respect to the dimensions and form, method of securement, and materials, these differences do not raise any new questions of safety or effectiveness, as confirmed by preclinical and clinical evaluation. Therefore, Permacol™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2002

Tissue Science Laboratories, PLC
c/o Howard M. Holstein, Esq.
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K013625
Trade/Device Name: Permacol
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM
Dated: November 01, 2001
Received: November 05, 2001

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((21CFR 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) 6382041 or (301) 4436597 or at its Internet address HYPERLINK http://www.fda.gov/cdrh/dsma/dsmamain.html http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

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

510(k) Number (if known): K013625

Device Name: Permacol™ Porcine Collagen Surgical Mesh

Indications For Use:

Permacol™ tissue is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for plastic and reconstructive surgery of the face and head.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K013625

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

(Optional Format 1-2-96)