K992556

FEB 17 2000

510(k) Summary

Sponsor: Tissue Science Laboratories, PLC
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Aldershot
Hants GU11 1SJ
United Kingdom

Contact Person:

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Submission Date: July 31, 1999

Device Name: Permacol™

Classification: Polymeric Surgical Mesh

Predicate Devices:
GraftPatch®
Rapi-Seal™ Patch
Biosynthetic Surgical Mesh
Peri-Guard® family of products
Glycar Tissue Repair Patch

Device Description:

Permacol™ is a sterile, tough, off-white, moist, flexible, fibrous flat sheet solely comprised of acellular crosslinked porcine dermal collagen and elastin

Intended Use:

Permacol™ 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 use in the following types of soft tissue repair procedures:

- abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical, and incisional hernias;
- colon, rectal, urethral, and vaginal prolapse;
- muscle flap reinforcement;
- reconstruction of the pelvic floor;
- sacrocolposuspension; and
- urethral sling.

Substantial Equivalence:

Permacol™ is substantially equivalent to the predicate devices in terms of its intended use, specific indications, and performance. There are minor differences in the technological characteristics, but laboratory and animal testing as well as clinical experience have shown that these do not raise any new concerns of either safety or effectiveness.

Safety Evaluation:

Standard biocompatibility testing was performed according to the FDA-modified matrix recommended in FDA memorandum #G95-1. The product passed all of the following tests:

Hemolysis
Cytotoxicity – elution method
Acute Systemic Toxicity
Implantation/Subchronic Toxicity
Genotoxicity – Ames Mutagenesis
Genotoxicity – Bone Marrow Micronucleus
Genotoxicity – Mouse Lymphoma Mutagenesis
Sensitization-Magnusson and Kligman
Pyrogenicity
Intracutaneous Reactivity

In addition to standard biocompatibility testing, a histological evaluation of the material after implantation in rats for 6 months demonstrated that Permacol™ is safe and well tolerated.

Clinical Evaluation:

Clinical experience in several hundred patients in Europe also has demonstrated that Permacol™ is safe and well tolerated. Case histories for 60 patients undergoing a variety of soft tissue repair procedures demonstrate that Permacol™ is easy to handle, and successful clinical outcomes were achieved in nearly all cases. No product-related adverse effects were noted in any of the procedures.

Conclusions Drawn:

Permacol™ is biocompatible, safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2000

Tissue Science Laboratories, PLC
c/o Mr. Howard M. Holstein, Esq.
Hogan & Hartson, LLP
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K992556
Trade Name: Permacol™
Regulatory Class: II
Product Code: FTL
Dated: December 22, 1999
Received: December 22, 1999

Dear Mr. Holstein:

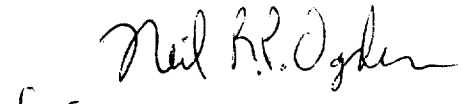
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

510(k) Number (if known): K992556
Device Name: Permacol™

Indications for Use:

Permacol™ 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 the repair of abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical and incisional hernias; colon, rectal, urethral and vaginal prolapse; muscle flap reinforcement; reconstruction of the pelvic floor and procedures such as sacrocolposuspension and urethral sling.

NPO for JZD
(Division Sign-Off)
Division of General, Restorative Devices
510(k) Number K992556

(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 CFR 801.109)

(Optional Format 1 – 2.96)
(Form prepared by The Wren Group)