510(k) Summary

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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
Permacol™ Porcine Collagen Surgical Mesh
510(k) Premarket Notification Submission

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;
- sacrocolpoposuspension; 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.
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,

[Signature]

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
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 hemias; colon, rectal, urethral and vaginal prolapse; muscle flap reinforcement; reconstruction of the pelvic floor and procedures such as sacrocolposuspension and urethral sling.