MAR 9 - 2005

K050355

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510(k) SUMMARY

Tissue Science Laboratories PLC, Permacol® Surgical Implant T-piece and Permacol® Surgical Implant Rectocele-piece

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

Victoria Taylor
Tissue Science Laboratories PLC
1141 Clark Street Suite D
Covington, Georgia 30014
USA
Tel: (678) 342 – 7808
Fax: (678) 342 – 7844
Email: vtaylor@tissuescience.com

Contact Person: Victoria Taylor

Date Prepared: 11th February 2005

Name of Device and Name/Address of Sponsor

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

Trade Name

Permacol® Surgical Implant T-piece
Permacol® Surgical Implant Rectocele-piece

Common or Usual Name

Surgical Mesh

Classification Name

Surgical Mesh

K050355

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Predicate Devices

Permacol® Crosslinked Porcine Dermal Collagen Surgical Mesh (K992556) and Permacol® Surgical Implant (K043366)

Intended Use

Permacol® Surgical Implants are intended for use to support/reinforce soft tissue in surgical procedures. Permacol® Surgical Implant T-pieces are shaped for use in rectal intussusception repair and Permacol® Surgical Implant Rectocele-pieces are shaped for use in rectocele repair.

Technological Characteristics and Substantial Equivalence

Permacol® T-piece and Permacol® Rectocele-piece are substantially equivalent to the predicate devices because they have the same intended uses and very similar technological characteristics.

Performance Data

Biocompatibility and bench studies have been completed and support the safety and effectiveness of Permacol® Surgical Implant for its intended use, therefore data supporting the biocompatibility of Permacol® Surgical Implant T-piece and Permacol® Surgical Implant Rectocele-piece is incorporated by reference.

The biocompatibility test results show that the material used in the design and manufacture of the devices are non-toxic and non-sensitizing to biological tissues consistent with their intended use. Laboratory test results demonstrate that the materials chosen and the design utilized in manufacturing Permacol® Surgical Implant T-piece and Permacol® Surgical Implant Rectocele-piece will meet the established specification necessary for consistent performance during their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Victoria Taylor
Associate Director of Regulatory Affairs
Tissue Science Laboratories, PLC
1141 Clark Street, Suite D
COVINGTON GA 30014

SEP 28 2012

Re: K050355
Trade/Device Name: Permacol® Surgical Implant T-piece
Permacol® Surgical Implant Rectocele-piece
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAI
Dated: February 11, 2005
Received: February 14, 2005

Dear Ms. Taylor:

This letter corrects our substantially equivalent letter of March 9, 2005.

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 (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 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.

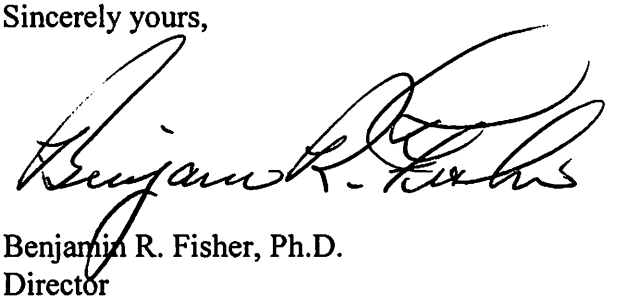
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K050355

Indications for Use

510(k) Number (if known): K050355

Device Name: Permacol® Surgical Implant T-piece
Permacol® Surgical Implant Rectocele-piece

Indications for Use:
Permacol® Surgical Implants are intended for use to support/reinforce soft tissue in surgical procedures. Permacol® Surgical Implant T-pieces are shaped for use in rectal intussusception repair and Permacol® Surgical Implant Rectocele-pieces are shaped for use in rectocele repair.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050355