510(k) Summary

This 510(k) summary for Xenform is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by

TEI Biosciences Inc.
7 Elkins Street
Boston, MA 02127
(617) 268-1616
(617) 268-3282 (fax)

Contact Person

Kenneth James, Ph.D.
Vice President, Product Sciences and Regulatory Affairs

Date Prepared

March 30, 2006

Device Information

Proprietary name:	Xenform
Classification name:	Surgical Mesh
Device classification:	Class II

Device Description

Xenform Soft Tissue Repair Matrix is an acellular collagen material intended to be utilized for surgical procedures pertaining to the pelvic floor. Xenform Soft Tissue Repair Matrix is supplied sterile and provided in sheet form in a variety of sizes to be trimmed and sutured by the surgeon to meet the individual patient's needs. Xenform Soft Tissue Repair Matrix is manufactured from bovine skin, one of the purest sources of collagen available. The source material is solely derived from cattle obtained in compliance with US and European regulatory requirements.

Intended Use

Xenform Soft Tissue Repair Matrix 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 colon, rectal, urethral, and vaginal prolapse; reconstruction of the pelvic floor; and procedures such as sacrocolposuspension and urethral sling.

Legally Marketed Devices to which Equivalence is Being Claimed

Xenform is substantially equivalent in function and intended use to:

Predicate Devices	Manufacturer	510(k) Number
Xenform	TEI Biosciences	K051190

Summary of Technological Characteristics and Biocompatibility

Xenform Soft Tissue Repair Matrix is substantially equivalent to other surgical meshes with respect to its design as a thin, flexible, polymeric sheet which can be sutured to surrounding tissues to secure it in place. In addition, the device is fully resorbable over a period of months.

A rigorous biocompatibility assessment performed by an independent certified laboratory demonstrated the biocompatibility of Xenform. The tests performed included: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, genotoxicity, intramuscular toxicity, hemolysis, and pyrogenicity. The manufacturing methods for Xenform were also tested by an independent laboratory to assure safe levels of viral inactivation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2006

TEI Biosciences Inc.
% Kenneth James, Ph.D.
VP, Product Sciences and Regulatory
Affairs
7 Elkins Street
Boston, Massachusetts 02127

Re: K060984
Trade/Device Name: Xenform
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: March 30, 2006
Received: May 1, 2006

Dear Dr. James:

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060984

Device Name: Xenform

Indications For Use:

Xenform Soft Tissue Repair Matrix 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 colon, rectal, urethral, and vaginal prolapse; reconstruction of the pelvic floor; and procedures such as sacrocolposuspension and urethral sling.

Prescription Use √ 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 K060984