K031188/P1/2

510(k) Summary

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

Submitted by

TEI Biosciences Inc.
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Contact Person

Kenneth James, Ph.D.
Director of Product Development and Applied Research

Date Prepared

June 25, 2003

Device Information

Proprietary name: OrthoMend
Classification name: mesh, surgical, polymeric
Device classification: Class II (21CFR878.3300)

Device Description

OrthoMend is a remodelable collagen matrix used to reinforce soft tissues where weakness exists. The device is supplied sterile and is provided in sheet form in a variety of sizes to be trimmed and sutured by the surgeon to meet the individual patient's needs.

Intended Use

OrthoMend is intended for surgical implantation to reinforce soft tissue where weakness exists and for the repair of damaged or ruptured soft tissue membranes. In addition, the device is intended to reinforce soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff surgery.

Legally Marketed Devices to which Equivalence is Being Claimed

OrthoMend™ is substantially equivalent in function and intended use to:

Predicate Devices	Manufacturer	510(k) Number
TissueMend Soft Tissue Repair Matrix	TEI Biosciences, Boston, MA	K020455
Restore Orthobiologic Soft Tissue Implant	DePuy, Warsaw, IN	K001738

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Summary of Technological Characteristics and Biocompatibility

OrthoMend™ 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 OrthoMend™. The tests performed included: cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, genotoxicity, intramuscular toxicity, hemolysis, and pyrogenicity. The manufacturing methods for OrthoMend™ 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

JUN 27 2003

Kenneth James, Ph.D.
Director of Product Development
and Applied Research
TEI Biosciences, Inc.
7 Elkins Street
Boston, Massachusetts 02127

Re: K031188
Trade/Device Name: OrthoMend
Regulation Number: 21 CFR 878.3300
Regulation Name: mesh, surgical, polymeric
Regulatory Class: II
Product Code: FTL
Dated: April 8, 2003
Received: April 16, 2003

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 (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) you may obtain. 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) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for 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

2. Indications for Use of the Device

510(k) Number (if known): K031188

Device Name: OrthoMend

Indications for Use: OrthoMend is intended for surgical implantation to reinforce soft tissue where weakness exists and for the repair of damaged or ruptured soft tissue membranes. In addition, the device is intended to reinforce soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff surgery.

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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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031188