K033115
P1/2

NOV 17 2003

SECTION VI

510(k) Summary

Substantial Equivalence

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer

Teleflex Medical
600 Airport Road
Fall River, MA 02720-4740

Contact Person

Stephen Page
Phone: (508) 677-6543
Fax: (508) 677-6663
E-mail: spage@teleflexmedical.com

Date Prepared

October 27, 2003

Device Information

Trade Name:	Orthodek™ Poly(L-lactide) Synthetic Absorbable Surgical Suture.
Common Name:	Poly (L-lactide) Synthetic Absorbable Surgical Sutures.
Classification Name:	Absorbable Poly (glycolide/L-lactide) Surgical Suture.

Indications for Use

Orthodek™ Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and /or ligation, and orthopedic uses including tendon and ligament repairs and reattachment to bone but not for use in ophthalmic, cardiovascular or neurological tissue. Orthodek suture is particularly useful where extended wound support (up to 6 months) is desirable.

Device Description

Orthodek Poly (L-lactide) Absorbable Surgical Suture meets all USP requirements except for oversized diameter. Orthodek is available in size 2 (metric size 5) undyed (white). The suture is a sterile, braided multifilament, is provided in a variety of lengths, with or without needles, and may be supplied in a variety of cut lengths or on ligating reels.

K033115 p2/2

SECTION VI

510(k) Summary (Cont.)

Substantial Equivalence

The device is similar in intended use, materials, design, and performance characteristics to the cleared Ethicon Panacryl Absorbable Surgical Suture (K974299). Minor differences between the Teleflex Medical Suture and predicate devices do not raise any questions concerning safety and effectiveness and have no apparent effect on the performance, function or intended use of this device.

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ANSI/AAMI/ISO 10993-1 Biological Evaluation of Medical Devices, USP Section XXVI - Absorbable Surgical Sutures, Guidance Document "Guidance for Surgical Suture 510(k) s" issued on August 10, 2000 and the FDA "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA", June 3, 2003.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2003

Mr. Stephen Page
Director, Regulatory Affairs
Teleflex Medical
600 Airport Road
Fall River, Massachusetts 02720

Re: K033115
Trade/Device Name: Orthodeck™ Synthetic Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: II
Product Code: GAM
Dated: September 22, 2003
Received: September 30, 2003

Dear Mr. Page:

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. 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,

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

K033115

510(k) Number (if known)

Device Name

Orthodek Poly(L-lactide)
Absorbable Surgical Suture

Indications for Use

Orthodek™ Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and /or ligation, and orthopedic uses including tendon and ligament repairs and reattachment to bone but not for use in ophthalmic, cardiovascular or neurological tissue. Orthodek suture is particularly useful where extended wound support (up to 6 months) is desirable.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ 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 K033115