K040472

MAR 15 2004

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Teleflex Medical submits this summary of safety and effectiveness.

1. Submitter Name, Address, and Date of Submission

Angela Tran
Regulatory Affairs Supervisor
Teleflex Medical
2917 Weck Drive
Research Triangle Park, NC 27709
Telephone: (919) 361-4008
Facsimile: (919) 361-3966
Submitted: February 23, 2004

2. Name of the Device, Common, Proprietary (if known), and Classification

Classification Name:	Suture
Common Name:	Suture
Proprietary Name:	Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture
Classification:	Class II, 21CFR §878.5000

3. Identification of the legally marketed device to which the submitter claims equivalence

The Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture described in this submission is substantially equivalent to previously cleared suture, Force Fiber Polyethylene Non-Absorbable Surgical Suture.

4. Description of the Device

The Force Fiber Blue Co-Braid Polyethylene is non-absorbable, sterile, surgical suture composed of ultra high molecular weight polyethylene (UHMWPE). It is available in sizes 2-0 through 2 meeting USP requirements except for oversized diameter.

5. Intended Use of the Device

The Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture is intended to approximate and/or ligate soft tissues, including the use of allograft tissue for orthopaedic surgeries.

6. Summary of Technological Characteristics

The technological characteristics are the same as or equivalent to the predicate device. The dimensional specification change does not adversely affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 5 2004

Ms. Angela Tran
Regulatory Affairs Supervisor
Teleflex Medical
2917 Weck Drive
Research Triangle Park, North Carolina 27709

Re: K040472
Trade/Device Name: Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: February 16, 2004
Received: February 24, 2004

Dear Ms. Tran:

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

Indications for Use

510(k) Number (if known): K040472

Device Name: Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture

Indications For Use: Force Fiber Blue Co-Braid Polyethylene Non-Absorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including the use of allograft tissue for orthopaedic surgeries.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K040472