SEP 15 2009

SECTION 8 - 510(K) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Force Fiber® Blue Polyethylene Non-Absorbable Surgical Sutures

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical Incorporated
5307 95th Avenue
Kenosha, WI 53144
Phone: 262-925-8274
Fax: 262-657-2801
E-mail: jvoigt@teleflexmedical.com

B. Contact Person

Joy Voigt
Regulatory Affairs Manager

C. Date Prepared

17 July 2009

D. Device Name

Trade Name:
Force Fiber® Blue Ultra High Molecular Weight Polyethylene Non-Absorbable Surgical Suture

Common Name: Polyethylene Synthetic Non-Absorbable Surgical Suture

Classification Name: Nonabsorbable poly(ethylene terephthalate) surgical suture

E. Device Description

The Force Fiber® Polyethylene is non-absorbable, sterile, surgical suture composed of ultra high molecular weight polyethylene (UHMWPE). It is available as 100% blue (UHMWPE), sizes 0, 1 and 2 meeting USP requirements except for oversized diameter.

F. Indications for Use

Force Fiber® Blue Ultra High Molecular Weight Polyethylene Non-Absorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use in cardiovascular surgeries and the use of allograft tissue for orthopaedic surgeries.

G. Substantial Equivalence

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The device has the same intended use and fundamental scientific technology as Teleflex Medical Force Fiber® Polyethylene Non-absorbable Surgical Suture (K063778). The determination of substantial equivalence for this device was based on a detailed device description, performance testing, and conformance with voluntary performance standards.

H. Summary of Testing

All sizes of Force Fiber® Blue Ultra High Molecular Weight Polyethylene Non-Absorbable Surgical Suture have been tested in accordance with USP 31 – Non-absorbable Surgical Sutures for Knot Pull Tensile Strength, Needle Attachment and Diameter, and meet the requirements of the *Class II Special Controls Guidance: Surgical Sutures*; Guidance for Industry and FDA; June 3, 2003.

All materials used in the fabrication of the Force Fiber® Blue Ultra High Molecular Weight Polyethylene Non-Absorbable Surgical Suture were evaluated through biological qualification safety tests as outlined in ISO 10993-1:2003, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 15 2009

Teleflex Medical
% Ms. Joy Voigt
Manager, Regulatory Affairs
5307 95th Avenue
Kenosha, Wisconsin 53144

Re: K092533
Trade/Device Name: Force Fiber® Blue Ultra High Molecular Weight Polyethylene Non-Absorbable Surgical Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: August 18, 2009
Received: August 19, 2009

Dear Ms. Voigt:

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 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" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Force Fiber® Blue Ultra High Molecular Weight Polyethylene Non-Absorbable Surgical Suture

Indications for Use:

Force Fiber® Polyethylene Non-Absorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use in cardiovascular surgeries and the use of allograft tissue for orthopaedic surgeries.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092533