DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 3, 2017

Teleflex Medical Incorporated
Ms. Vladislava Zaitseva
Senior Regulatory Affairs Specialist
375 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K172016
Trade/Device Name: Force Fiber Fusion Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: June 30, 2017
Received: July 3, 2017

Dear Ms. Zaitseva:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172016

Device Name
Force Fiber Fusion™ Suture

Indications for Use *(Describe)*
Force Fiber Fusion™ Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopaedic surgeries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary of Safety and Effectiveness

This 510(k) Summary for Teleflex Force Fiber Fusion™ Suture is provided as required by section 807.92(c).

Sponsor/Applicant:	Teleflex Medical Inc. 375 Forbes Boulevard Mansfield, MA 02048 USA FDA Establishment Registration #: 1221601
Date Prepared:	September 7, 2017
Contact:	Vladislava Zaitseva Senior Regulatory Affairs Specialist, OEM Phone: 1-508-964-6030 Fax: 1-508-964-6078 vladislava.zaitseva@teleflex.com
Proprietary Name:	Force Fiber Fusion™ Suture
Common Name:	Polyethylene synthetic non-absorbable surgical sutures
Classification Name:	Suture, nonabsorbable, synthetic, polyethylene
Regulation Number:	21CFR § 878.5000
Product Code:	GAT
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

Device Description

Force Fiber Fusion suture is an uncoated braid offered in a variety of cut lengths, with or without needles, and provided sterile for single use only. Force Fiber Fusion Suture is braided to transition from round suture to tape suture and back to round suture within the same braid construction. The tape section(s) are flat in shape and differ from USP requirements. The round section(s) exceed USP for diameter. The suture meets USP tensile strength requirements and USP needle attachment requirements. Force Fiber Fusion suture is available in sizes 1 through 5 and composed of undyed or blue Ultra High Molecular Weight Polyethylene (UHMWPE), UHMWPE/blue polyester co-braid, UHMWPE/black Nylon co-braid or UHMWPE/green Polyester co-braid.

Indications for Use

Force Fiber Fusion suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopaedic surgeries.

Substantial Equivalence

Force Fiber Fusion suture is substantially equivalent in intended use and fundamental scientific technology to its primary predicate Force Fiber OrthoTape suture cleared under K150438 on 04/02/2015. The other listed predicates are part of the same Force Fiber suture family cleared under 510(k)s K063778 on 2/09/2007, K070673 on 4/2/2007, K092533 on 9/15/2009, and K100506 on 3/10/2010.

Technological Characteristics

Force Fiber Fusion suture is substantially equivalent to its predicate device Force Fiber OrthoTape suture cleared under K150438, and other Force Fiber suture predicates cleared under K063778, K070673, K092533, K100506 based on the same intended use, and the following commonalities in technological characteristics:

- Same UHMWPE, PP, PET and Nylon materials are used in the manufacture of proposed and predicate devices.
- Both, proposed and predicates, have braided configurations.
- Both, Force Fiber and Force Fiber Fusion, are oversized for diameter.
- The test method used to confirm the performance specifications of tensile strength and needle attachment for both the proposed and predicate devices were conducted in accordance with USP requirements.

The difference between proposed Force Fiber Fusion and the currently legally marketed Force Fiber and Force Fiber OrthoTape sutures is that Force Fiber Fusion Suture is braided to transition from round suture to tape suture and back to round suture within the same braid construction. This difference does not raise new questions of safety or efficacy. The proposed Force Fiber Fusion suture is substantially equivalent in intended use and fundamental scientific technology to the Force Fiber and Force Fiber OrthoTape predicate devices.

Summary of Testing

Force Fiber Fusion suture is tested in accordance with USP - non-absorbable surgical sutures for tensile strength and needle attachment, 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 Fusion suture were evaluated through biological qualification safety tests as outlined in AAMI ANSI ISO 10993-1: 2009/(R) 2013 -- *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*.

Conclusion

Based upon the comparative test results, the proposed Force Fiber Fusion Sutures are substantially equivalent in performance to the legally marketed predicate devices.