June 11, 2019

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

Re: K191268
Trade/Device Name: Force Fiber Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: May 10, 2019
Received: May 13, 2019

Dear Ms. Andrea Curria:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For David Krause, Ph.D.
Acting Division Director
Division of Infection Control and Plastic Surgery Devices
Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name Force Fiber® Suture

Indications for Use *(Describe)*

Force Fiber® 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 orthopedic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 8 – 510(k) Summary

510(k) Summary of Safety and Effectiveness

This 510(k) Summary for Teleflex Force Fiber® Suture – Black 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: May 10, 2019

Contact: Andrea Curria
Senior Regulatory Affairs Specialist, OEM
Phone: 1-508-964-6030
Fax: 1-508-964-6078
Andrea.curria@teleflex.com

Proprietary Name: Force Fiber® Suture

Common Name: Polyethylene nonabsorbable surgical suture

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 Suture - Black is a non-absorbable, sterile, surgical suture composed of Ultra High Molecular Weight Polyethylene (UHMWPE) dyed black using D&C Black #4 not to exceed 1.0% by weight. It is an uncoated braid offered in a variety of cut lengths, with or without needles, and provided sterile for single use only. Force Fiber Suture - Black is available in sizes 0, 1 and 2, and meets all surgical suture requirements established by the USP for non-absorbable surgical sutures except for oversize diameter.

Section 8 – 510(k) Summary

Indications for Use

Force Fiber Suture – Black is 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.

Substantial Equivalence

Force Fiber Suture - Black is substantially equivalent in intended use and fundamental scientific technology to the Force Fiber Suture predicate devices cleared under 510(k) #K033654 on 1/15/2004, K063778 on 2/09/2007, K070673 on 4/2/2007, K092533 on 9/15/2009, K100506 on 3/10/2010 and K181774 on 10/10/2018.

Technological Characteristics

Force Fiber Suture – Black is substantially equivalent to its predicate Force Fiber Suture devices because there are no differences in technological characteristics and performance characteristics between the proposed and predicate devices. The proposed sutures have the same fundamental design and intended use as the predicate devices.

The difference between Force Fiber Suture – Black and its predicate Force Fiber Suture devices is the addition of black dye (D&C Black #4 not to exceed 1.0% by weight) to the white UHMWPE fibers. This difference does not raise new questions of safety or efficacy. Therefore, Force Fiber Suture - Black is as safe and effective as its currently marketed predicate devices.

Summary of Testing

Force Fiber Suture - Black is tested in accordance with USP - non-absorbable surgical sutures for suture diameter, 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 Suture - Black were evaluated through biological qualification safety tests as outlined in ISO 10993-1: 2018 -- *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*.

Force Fiber Suture - Black is tested to demonstrate it is “MR Safe” and poses no known hazards in MR environments.