Dear Ms. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Peter L. Hudson -S
2018.10.10 15:42:23 -04'00'

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
Indications for Use

510(k) Number (if known)
K181774

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)
- [x] 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
PRASStaff@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.”
510(k) Number (if known)
K181774

Device Name
Force Fiber®OrthoTape® Suture

Indications for Use (Describe)
Force Fiber®OrthoTape® Suture is indicated for use in approximation and/or ligation of soft tissues, including 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)

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510(k) Number (if known)
K181774

Device Name
Bondek® and Bondek® Plus Suture

Indications for Use (Describe)
Bondek® and Bondek® Plus Synthetic Absorbable Surgical Sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

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

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

Monodek Monofilament Synthetic Absorbable Surgical Sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. Monodek® suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

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)

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510(k) Number *(if known)*  
K181774

Device Name  
Polyglytone*6211™ Suture

Indications for Use *(Describe)*  
Polyglytone*6211™ Monofilament Synthetic Absorbable Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular surgery, neurological surgery, or microsurgery.

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)

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- Office of Chief Information Officer  
- Paperwork Reduction Act (PRA) Staff  
- PRASTaff@fda.hhs.gov

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**510(k) Summary of Safety and Effectiveness**

This 510(k) Summary for Teleflex Surgical Sutures is provided as required by section 807.92(c).

**A. Sponsor/Applicant:** Teleflex Medical Inc.
375 Forbes Boulevard
Mansfield, MA 02048 USA
FDA Establishment Registration #: 1221601

**B. Date Prepared:** June 20, 2018

**C. Contact:** Andrea Curria
Regulatory Affairs Specialist, OEM
Phone: 1-508-964-6030
Mobile 1-401-529-0233
Fax: 1-508-964-6078
Andrea.Curria@teleflex.com

**D. Device Name**

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>Common Name</th>
<th>Classification Name</th>
<th>Regulation Number</th>
<th>Product Code</th>
<th>Device Class</th>
<th>Classification Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force Fiber® Suture</td>
<td>Suture, Nonabsorbable, Synthetic, Polyethylene</td>
<td>Suture, Nonabsorbable, Synthetic, Polyethylene</td>
<td>21CFR § 878.5000</td>
<td>GAT</td>
<td>Class II</td>
<td>General and Plastic Surgery</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Proprietary Name</th>
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<th>Regulation Number</th>
<th>Product Code</th>
<th>Device Class</th>
<th>Classification Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force Fiber® OrthoTape® Suture</td>
<td>Suture, Nonabsorbable, Synthetic, Polyethylene</td>
<td>Suture, Nonabsorbable, Synthetic, Polyethylene</td>
<td>21CFR § 878.5000</td>
<td>GAT</td>
<td>Class II</td>
<td>General and Plastic Surgery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>Common Name</th>
<th>Classification Name</th>
<th>Regulation Number</th>
<th>Product Code</th>
<th>Device Class</th>
<th>Classification Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bondek® and Bondek® Plus Suture</td>
<td>Suture, Absorbable, Synthetic, Polyglycolic Acid</td>
<td>Suture, Absorbable, Synthetic, Polyglycolic Acid</td>
<td>21CFR § 878.4493</td>
<td>GAM</td>
<td>Class II</td>
<td>General and Plastic Surgery</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>Common Name</th>
<th>Classification Panel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monodek® Suture</td>
<td>Suture, Surgical, Absorbable, Polydioxanone</td>
<td></td>
</tr>
</tbody>
</table>
Classification Name: Suture, Surgical, Absorbable, Polydioxanone
Regulation Number: 21CFR § 878.4840
Product Code: NEW
Device Class: Class II
Classification Panel: General and Plastic Surgery

Proprietary Name: Polyglytone*6211™ Suture
Common Name: Suture, Absorbable, Synthetic, Polyglycolic Acid
Classification Name: Suture, Absorbable, Synthetic, Polyglycolic Acid
Regulation Number: 21CFR § 878.4493
Product Code: GAM
Device Class: Class II
Classification Panel: General and Plastic Surgery

E. Device Descriptions

**Force Fiber Suture** is a non-absorbable, sterile, surgical suture composed of Ultra High Molecular Weight Polyethylene (UHMWPE). It is available as follows:

Table 1: Force Fiber suture available configurations

<table>
<thead>
<tr>
<th>Force Fiber color</th>
<th>Material</th>
<th>Available USP sizes</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>Braided undyed (white) UHMWPE fibers.</td>
<td>5-0 through 5</td>
</tr>
<tr>
<td>Blue</td>
<td>Braided blue UHMWPE fibers. The blue colorant is Chromium-cobalt-aluminum oxide &lt; 2.0% by weight per 21 CFR 73.1015.</td>
<td>0, 1, 2</td>
</tr>
<tr>
<td>White/Blue</td>
<td>Co-braid of white UHMWPE and blue polypropylene (PP) monofilament strands. The blue colorant is [phthalocyaninato (2-) copper &lt; 0.5% by weight per 21 CFR 74.3045.</td>
<td>5-0 through 5</td>
</tr>
<tr>
<td>White/Black</td>
<td>Co-braid of white UHMWPE fibers and black Nylon monofilament strands. The black colorant is logwood extract &lt; 1.0% by weight per 21 CFR §73.1410.</td>
<td>5-0 through 5</td>
</tr>
<tr>
<td>White/Green</td>
<td>Co-braid of white UHMWPE fibers and green polyester (PET) fibers. The green colorant is D&amp;C Green #6 &lt; 0.75% by weight per 21 CFR 74.3206. It should be noted that Force Fiber® Green Co-braid may appear blue in color under certain lighting conditions.</td>
<td>0, 1, 2</td>
</tr>
</tbody>
</table>

Force Fiber surgical sutures meet all surgical suture requirements established by the USP for non-absorbable surgical sutures except for oversized diameter.
**Force Fiber OthoTape Suture** is an uncoated braid that is flat in shape and differs from USP requirements (not USP). It is available in 1mm, 1.5mm, 2mm, 2.5mm, 3.5mm, 4mm and 5mm tape sizes and composed of undyed or blue Ultra High Molecular Weight Polyethylene (UHMWPE), or UHMWPE/ Green Polyester co-braid. Force Fiber OrthoTape suture sizes meet USP tensile strength requirements and USP needle attachment requirements for USP size #2 suture.

**Bondek and Bondek Plus Suture** is an absorbable, braided multifilament suture composed of a homopolymer of glycolic acid, polyglycolic acid. The Bondek suture material is coated with polycaprolactone-glycerol monostearate solution, and is available in green and beige (undyed) USP sizes 8-0 through 2. The Bondek Plus suture material is coated with polycaprolactone-co-polyglycolic acid, and is available in violet, green or beige (undyed) USP sized 6-0 through 2.

**Monodek** Absorbable Surgical Suture is a monofilament suture that meets all USP requirements except for oversize diameter. Monodek is available in sizes 6-0 through 0 (metric sizes 0.7 through 3.5), undyed and dyed (violet). The suture may be supplied on ligating reels.

**Polyglytone* 6211** suture, U.S.P size 2-0, is available, undyed (natural). The suture is monofilament, and may be provided with or without plegets.

The Teleflex surgical sutures are provided sterile (EO), for single use only and may be provided in a variety of cut lengths with or without needles. A variety of attached needles are available from either 300 or 400 series stainless steel.

**F. Indications for Use**

**Indications for Use:** 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.

**Contraindications:**
None known.

**Indications for Use:** Bondek® Synthetic Absorbable Surgical Sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

**Contraindications:**
None known.

**Indications for Use:** Bondek® and Bondek® Plus Synthetic Absorbable Surgical sutures are intended for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.
**Contraindications:** This suture, being absorbable, should not be used where extended approximation of tissue is required.

**Indications for Use:** Monodek® Monofilament Synthetic Absorbable Surgical Sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. Monodek® suture is not indicated in adult cardiovascular tissue, microsurgery and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to six weeks) is desirable.

**Contraindications:** These sutures, being absorbable, are not to be used where prolonged (beyond six weeks) approximation of tissues under stress is required and are not to be used in conjunction with prosthetic devices, i.e. heart valves or synthetic grafts.

**Indications for Use:** Polyglytone*6211™ Monofilament Synthetic Absorbable Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular surgery, neurological surgery, or microsurgery.

**Contraindications**
This suture, being absorbable, should not be used where extended approximation of tissue is required

---

### G. Substantial Equivalence

The proposed Teleflex Nonabsorbable and Absorbable Surgical Sutures are substantially equivalent to the predicate devices:

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>Manufacturer</th>
<th>510(k) No.</th>
<th>Date Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Force Fiber White and White Blue Co-Braid Polyethylene Non-Absorbable Surgical Suture</td>
<td>Teleflex Medical</td>
<td>K063778</td>
<td>2/09/2007</td>
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<tr>
<td>Force Fiber Black Co-Braid Polyethylene Non-Absorbable Surgical Suture</td>
<td>Teleflex Medical</td>
<td>K070673</td>
<td>4/2/2007</td>
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<tr>
<td>Force Fiber Blue Ultra High Molecular Weight Polyethylene Non Absorbable Sutures</td>
<td>Teleflex Medical</td>
<td>K092533</td>
<td>9/15/2009</td>
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<tr>
<td>Force Fiber Green Ultra High Molecular Weight Polyethylene Non Absorbable Sutures</td>
<td>Teleflex Medical</td>
<td>K100506</td>
<td>3/10/2010</td>
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<tr>
<td>Force Fiber OrthoTape Suture</td>
<td>Teleflex Medical</td>
<td>K150438</td>
<td>04/02/2015</td>
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<tr>
<td>Bondek Polyglycolic Acid Synthetic Absorbable Surgical Suture</td>
<td>Teleflex Medical</td>
<td>K991191</td>
<td>06/22/1999</td>
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<tr>
<td>Bondek Plus Polyglycolic Acid Synthetic Absorbable Surgical Suture</td>
<td>Teleflex Medical</td>
<td>K992088</td>
<td>09/03/1999</td>
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<tr>
<td>Monodek Synthetic Absorbable Surgical Suture</td>
<td>Teleflex Medical</td>
<td>K030212</td>
<td>03/27/2003</td>
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<tr>
<td>Polyglytone 6211 Synthetic Absorbable Suture</td>
<td>Teleflex Medical</td>
<td>K042141</td>
<td>09/28/2004</td>
</tr>
</tbody>
</table>
H. Technological Characteristics

Teleflex Surgical Sutures are equivalent to the marketed predicate 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 addition of an MR Safety statement does not raise new questions of safety or efficacy. The proposed Teleflex Surgical Sutures are substantially equivalent in intended use and fundamental scientific technology to their predicate devices.

I. Summary of Testing

Teleflex Surgical Sutures are not intended for use in the MR Environment. However, permanently implanted devices are subject to MR conditions. Non-clinical testing was completed to demonstrate the “MR Safe” claim. Teleflex Surgical Sutures are “MR Safe” and pose no known hazards in MR environments. The Indication for Use (IFU) inserts are being updated to include the “MR Safe” claim.

Conclusion

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