May 06, 2026

Teleflex Medical, LLC
Rebecca Walker
Sr. Regulatory Affairs Specialist
Contact Address

Re: K260775
Trade/Device Name: Polyethylene;Polyethylene Fusion;Polyethylene OrthoTape™
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: March 11, 2026
Received: March 10, 2026

Dear Rebecca Walker:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260775

Device Name
Polyethylene;
Polyethylene Fusion;
Polyethylene OrthoTape™

Indications for Use *(Describe)*
Polyethylene Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Polyethylene Fusion Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Polyethylene 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

Teleflex Polyethylene Sutures

K260775

Prepared on: April 16, 2026
Applicant Name: Teleflex Medical, LLC
3015 Carrington Mill Blvd.
Applicant Contact: Laura Medlin
Laura.Medlin@teleflex.com
919-544-8000
Correspondent: Rebecca Walker
Rebecca.Walker@teleflex.com
919-544-8000

1. Device Name

Device Trade Name: Teleflex Polyethylene Suture
Teleflex Polyethylene Fusion Suture
Teleflex Polyethylene OrthoTape™ Suture

Common Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Classification Name: Suture, Nonabsorbable, Synthetic, Polyethylene
Regulation Number: 21 CFR 878.5000
Product Code(s): GAT

2. Legally Marketed Predicate Devices

Predicate 510(k) #	Predicate Trade Name (Primary Predicate is listed first)	Predicate Product Code
K181774	Teleflex Surgical Sutures (Force Fiber® Suture, Force Fiber® OrthoTape® Suture)	GAT
K172016	Force Fiber® Fusion Suture	GAT
K231163	Riverpoint HS Suture	GAT
K162310	Stryker XBraid TT Suture	GAT

3. Device Description Summary

Teleflex Polyethylene Sutures (Polyethylene Suture, Polyethylene Fusion Suture, and Polyethylene OrthoTape™ Suture) are braided multifilament made from up to 100% Ultra High Molecular Weight Polyethylene (UHMWPE). The Polyethylene Sutures are available in multiple colors and braid patterns which are used for multi-strand procedures, better visibility and suture differentiation during surgery. They are available multicolored or co-braided with nylon, polypropylene, or polyester. Teleflex Polyethylene Sutures consist of the following variants, differentiated by the braid type:

- **Polyethylene Suture**
  Polyethylene Sutures feature a round and coreless braid that will flatten upon itself, during the tying process, to provide a snug, low knot profile that allows precise knot placement and a smooth tie down. Polyethylene sutures meet USP with the exception of diameter (oversized).

- **Polyethylene Fusion Suture**
  Polyethylene Fusion Sutures are braided to transition from round coreless 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.

- **Polyethylene OrthoTape™ Suture**
  Polyethylene OrthoTape™ Sutures are flat in shape and differ from USP requirements. Polyethylene OrthoTape™ is designed to meet the Teleflex internally developed specifications for width, height, length, tensile strength, and needle attachment. All Polyethylene OrthoTape™ Suture sizes meet USP tensile strength requirements and USP needle attachment requirements for USP size #2 suture.

All three variants are available in a variety of lengths, with and without attached stainless steel needles. The finished sutures are provided sterile, for single use only and are packaged in cartons as single packs or multi-packs. Teleflex Polyethylene sutures, with the needles removed, are MR safe (i.e., an item that poses no known hazards in all MR environments).

The purpose of this submission is to add the following colors to the Teleflex Polyethylene Suture family:

- UHMWPE containing D&C Violet No. 2, ≤0.2% w/w
- UHMWPE containing Pigment Green 7 (phthalocyanine), ≤0.5% w/w

The violet and green UHMWPE colorants are offered in the following configurations for all variants:

- Solids (100% UHMWPE of violet, green)
- Violet or green co-braids with white polyester, green polyester, black nylon, or blue polypropylene
- Violet or green multicolor braids with blue, black or white UHMWPE

The Teleflex Polyethylene Suture, Polyethylene Fusion Suture, and Polyethylene OrthoTape™ Suture were formerly marketed by Teleflex as Force Fiber®, Force Fiber® Fusion Suture, and Force Fiber® OrthoTape™ Suture. This submission is removing private label brand names from labeling.

4. Intended Use/Indications for Use

Polyethylene Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Polyethylene Fusion Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Polyethylene OrthoTape™ Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

5. Substantial Equivalence

Indications for Use Comparison

The Teleflex Polyethylene Suture line extension has identical indications for use as the predicate device(s). Like the predicate Force Fiber and Force Fiber OrthoTape™ Sutures (cleared under Teleflex Surgical Sutures (K181774)) and Force Fiber Fusion Suture (K172016), the subject Polyethylene, Polyethylene Fusion and Polyethylene OrthoTape™ Sutures are all indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

Technological Comparison

The Teleflex Polyethylene Suture line extension has the same principles of operation, and similar technological characteristics as the predicate Force Fiber and Force Fiber OrthoTape™ sutures, cleared under K181774 and Force Fiber Fusion cleared under K172016. Both the subject and the predicate devices have the same USP performance requirements, are sterilized using the same processes, and are comprised of the same materials of construction. The difference in technological characteristics are limited to the addition of two new color additives on the UHMWPE Fibers, D&C Violet No. 2 and Pigment Green 7 (phthalocyanine), which has been added to all three braid variants within the Teleflex Polyethylene Sutures family. The table below provides cross-reference to the most recent 510(k) clearance for each Teleflex Polyethylene Suture variant, the colorants being added, and the reference devices in which the colorants have received 510(k) clearance.

Subject Device (Predicate 510(k))	Material/ Color	Colorant	% w/w	Reference Device for Colorant
Polyethylene Suture (K181774, K191268) Polyethylene Fusion (K172016) Polyethylene OrthoTape™ (K181774)	UHMWPE, Violet	D&C Violet No. 2	0.2%	Stryker XBraid TT (K162310) *Note*[1]
	UHMWPE, Green	Pigment Green 7 (phthalocyanine)	≤0.5%	Riverpoint Medical, HS Fiber Suture (K231163)

[1]*D&C Violet No. 2 at the same w/w has also been previously cleared for Teleflex Bondek™ Sutures (K181774) and Teleflex Monodek™ Sutures (K181774). These are absorbable sutures and have been included as reference.*

The addition of the violet and green UHMWPE to the Teleflex Polyethylene Suture family does not raise new questions on safety or effectiveness as demonstrated through predicate and reference device comparison and performance testing. Biological evaluation submitted for the predicate under K181774 has been leveraged to support biocompatibility. Additionally, the new colorants used have been cleared for UHMWPE sutures within the same indications for use .

6. Non-Clinical Testing

The Teleflex Polyethylene Sutures have been tested for conformance to the following internal and performance requirements as stated in the applicable special controls for surgical sutures:

- Sutures - Diameter <861>
- Sutures - Needle Attachment <871>

- Tensile Strength <881>
- Dimensional Requirements (Height, Width, Length)

Additionally, an evaluation of safety in the Magnetic Resonance (MR) environment to support the designation of MR Safe (without needles) was conducted.

The results of design verification and stability testing completed on the subject device confirm the Teleflex Polyethylene Sutures (Polyethylene Suture, Polyethylene Fusion Suture and Polyethylene OrthoTape™ Suture) have met all required performance requirements and are substantially equivalent to the predicate device.

7. Conclusions

The subject device does not raise new questions on safety or effectiveness as demonstrated through predicate comparison and performance testing presented in this 510(k). Teleflex Polyethylene Sutures (Polyethylene Suture, Polyethylene Fusion Suture and Polyethylene OrthoTape™ Suture) are substantially equivalent to the predicate device.