July 06, 2026

Teleflex Medical, LLC
Rebecca Walker
Sr. Regulatory Affairs Specialist
3015 Carrington Mill Blvd.
Morrisville, North Carolina 27560

Re: K261988
Trade/Device Name: Monodek™ (POLYDIOXANONE) Dyed Violet Monofilament Synthetic Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: Class II
Product Code: NEW
Dated: June 12, 2026
Received: June 12, 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)*
K261988

Device Name
MONODEK™ (POLYDIOXANONE) Dyed Violet Monofilament Synthetic Absorbable Surgical Suture

Indications for Use *(Describe)*
MONODEK™ Sutures are indicated for use in all types of soft tissue approximation. 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)

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.

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510(k) Summary

Teleflex

MONODEK™ (POLYDIOXANONE) Dyed Violet Monofilament Synthetic Absorbable Surgical Suture

K261988

Prepared on: July 09, 2026
Applicant Name: Teleflex Medical, LLC
3015 Carrington Mill Blvd.
Morrisville, NC 27560
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 MONODEK™ (POLYDIOXANONE) Dyed Violet Monofilament Synthetic Absorbable Surgical Suture

Common Name: Absorbable polydioxanone surgical suture
Classification Name: Suture, surgical, absorbable, polydioxanone
Regulation Number: 21 CFR 878.4840
Product Code(s): NEW

2. Legally Marketed Predicate Devices

Predicate 510(k) #	Predicate Trade Name (Primary Predicate is listed first)	Predicate Product Code(s)
K181774	Force Fiber White and White/Blue, White/Black, Blue, and White/Green sutures; Force Fiber OrthoTape suture; Bondek suture and Bondek Plus suture; Monodek suture; Polyglytone*6211 suture	GAT, GAM, NEW

3. Device Description Summary

The Teleflex Monodek™ (POLYDIOXANONE) Dyed Violet Monofilament Synthetic Absorbable Surgical Sutures are provided sterile (EO), for single use only. Monodek is available exclusively with

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USP 0 suture in a variety of suture lengths and configurations, with or without attached needles. The needles are manufactured from 300 or 400 series stainless steel. Attached needles may include a ½-circle taper point single flat body style curved needle that conforms to the applicable USP requirements for needle attachment strength, or a bullet needle with a taper-cutting point and a straight round-body style. The sutures have a shelf-life of 3 years. The finished suture may be packaged in cartons as single packs, multi-packs, or procedure packs.

Monodek™ (POLYDIOXANONE) Dyed Violet Monofilament Synthetic Absorbable Surgical Sutures conform to all requirement established by the USP for synthetic absorbable surgical sutures, except for oversized diameter, and the European Pharmacopeia (E.P.) for diameter for sterile synthetic absorbable sutures. The product labeling lists the specifications for the oversized diameter sutures.

4. Intended Use/Indications for Use

MONODEK™ Sutures are indicated for use in all types of soft tissue approximation. 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.

5. Substantial Equivalence

Indications for Use Comparison

The indications of the subject Monodek Suture have been narrowed, as compared to the previous clearance for the same suture to align with the sizes marketed. This change does not alter the device's intended use or technological characteristics in a way that raises new safety or effectiveness questions.

Technological Comparison

An alternate sterilization cycle (MC-1) has been qualified for the Monodek Sutures to comply with the requirements of the updated EPA regulations regarding air toxics standards for ethylene oxide commercial sterilization facilities (March 14, 2024). Additionally, this Special 510(k) includes a change in the primary packaging of the Monodek suture. This change implements a new Tyvek/Foil pouch single-barrier system, replacing the double barrier, Foil Paper/Clear film outer pouch.

The modified Monodek Suture has the same technological characteristics as the previously cleared suture. Monodek is available exclusively with USP 0 suture in a variety of suture lengths and configurations, with or without attached needles. Differences in primary packaging (sterile barrier) and sterilization cycle parameters do not introduce new risks and packaging. Sterilization and stability studies have been conducted in accordance with recognized standards. Additional minor modifications in labeling are not the result of a design change and do not have an impact on the intended use.

6. Non-Clinical Testing

Verification and validation activities conducted based on the risk assessment for the proposed changes are summarized below. The results demonstrate that the proposed changes do not adversely affect the safety or effectiveness of the subject device. The Teleflex Monodek Sutures continue to meet all applicable design and performance requirements and remain substantially equivalent to the predicate device.

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- Sterilization validation in accordance with BS EN ISO 11135:2014 Sterilization of healthcare products – Ethylene oxide: Requirements for development, validation and routine control of a sterilization process for medical devices was performed and EO residual testing was performed to demonstrate the cycle achieves a sterility assurance level (SAL) of 10-6 and the device meets the EO residual requirements as defined in BS EN ISO 10993-7:2008+A1:2022.
- The modified packaging was validated according to the same test methods as previously performed for the Monodek Sutures cleared under K181774, in accordance with BS EN ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1: requirements for materials, sterile barrier systems and packaging systems and ANSI/AAMI/ISO 11607-2 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes.
- To validate the 3-year shelf life in the modified packaging, product stability testing in accordance with USP (United States Pharmacopeia) Absorbable Sutures, 43 <861> Sutures – Diameter, <871> Sutures – Needle Attachment, <881> Tensile Strength, and Resorption was performed. Testing was conducted following the same test methods as previously performed on the Monodek Suture submitted under K181774.

7. Conclusions

The changes presented in this 510(k), which do not alter the intended use or fundamental scientific technology, are supported by the risk analysis and performance data following FDA-recognized consensus standards and the same testing as previously performed for the Monodek Sutures, most recently cleared under K181774, to demonstrate the modified device is substantially equivalent to the predicate.