May 28, 2026

Medtronic
Lacee Levesque
Regulatory Affairs Manager
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K253530
Trade/Device Name: Trexon™ Monofilament Synthetic Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: April 30, 2026
Received: April 30, 2026

Dear Lacee Levesque:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253530

Please provide the device trade name(s).

Trexon™ Monofilament Synthetic Absorbable Suture

Please provide your Indications for Use below.

Trexon™ Monofilament Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular and neurological surgery.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary
(K253530)

Date Prepared: May 28, 2026

Submitter:
Covidien IIc (subsidiary of Medtronic)
60 Middletown Ave
North Haven, CT 06473
United States

Contact:
Nicole Boroumand
Senior Regulatory Affairs Specialist
60 Middletown Ave
North Haven, CT 06473
United States
Telephone: (626) 375-3597
Email: Nicole.boroumand@medtronic.com

Subject Device:
Trade name: Trexon™ Monofilament Synthetic Absorbable Suture
Classification name: Suture, Absorbable, Synthetic, Polyglycolic Acid
Product Code/Registration: Product Code GAM
Regulation Number 21 CFR 878.4493

Predicate Device:
Trade/Proprietary name: Biosyn™ Monofilament Synthetic Absorbable Suture
Classification name: Suture, Absorbable, Synthetic, Polyglycolic Acid
Product Code/Registration: Product Code GAM
Regulation Number 21 CFR 878.4493

Predicate 510(k) Number: K000037

Manufacturer:
Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

Reason for 510(k): To obtain market clearance for Trexon™ Monofilament Synthetic Absorbable Suture.

Device Description: Trexon™ Monofilament Synthetic Absorbable Suture are absorbable implants intended by the manufacturer to provide strength and support during and after surgical interventions, where soft tissue approximation and/or ligation of tissues is

needed. The sutures are prepared from a synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate (dyed sutures also contain D&C Violet #2) and are absorbed in approximately 90-110 Days.

Trexon™ Monofilament Synthetic Absorbable Sutures are available in USP sizes 1 through 6-0, in lengths between 18 and 96 inches, and in single-packs, multi-packs, and wide-packs with or without needles. Needle types include 3/8 circle, ½ circle, 5/8 and straight.

Intended users are healthcare professionals who have been trained in applicable surgical procedures and approaches involving sutures prior to employing this device.

Indications for use:

Trexon™ Monofilament Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular and neurological surgery.

Substantial Equivalence:

	Subject Device Trexon™ Monofilament Synthetic Absorbable Sutures	**Predicate Device** Biosyn™ Monofilament Synthetic Absorbable Sutures K000037	**Reference Device** Monocryl™ Sutures K964072
Indications For Use	Trexon™ Monofilament Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular and neurological surgery.	Biosyn™ Monofilament Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation and/or ligation, including ophthalmic surgery, but not for use in cardiovascular and neurological surgery.	MONOCRYL™ Suture is indicated for use in general soft tissue approximation and/or ligation, except for cardiovascular and neurological tissues or for microsurgery or ophthalmic surgery
Contraindications	This suture, being absorbable, should not be used where extended	This suture, being absorbable, should not be used where extended approximation of tissue is required.	This suture (dyed and undyed), being absorbable, should not be used where extended approximation of

	approximation of tissue is required.		tissues under stress is required
Performance Specifications	2-week knot pull tensile strength: approximately 50-60% of USP and EP 3-week knot pull tensile strength: 25-35% of USP and EP	**Different** 2-week knot pull tensile strength: minimum of 75% of EP T0 standard 3-week knot pull tensile strength: minimum of 40% of EP T0 standard	**Different** 2-week knot pull tensile strength: approximately 30% to 40% (dyed) or 20% to 30% (undyed) 3-week knot pull tensile strength: N/A
Classification	Pannel number: 79 Product code: GAM, per 21 CFR 878.4493 Absorbable poly(glycolide/l-lactide) surgical suture	**Identical**	N/A
Materials	**Suture:** glycolide, dioxanone, and trimethylene carbonate	**Identical**	N/A
Size and color	USP sizes 1 through 6-0. Undyed or dyed violet.	**Identical**	N/A
Configurations	Pre-cut lengths, non-needled or affixed to needles using both permanent and removable needle attachment techniques.	**Identical**	N/A
Sterilization	ETO sterilization with a minimum Sterility Assurance Level (SAL) of 10^{-6}	**Identical**	N/A
Packaging	Molded racetrack retainer inside a single	**Different** Figure 8 paper retainer inside a foil pouch	N/A

	barrier end peel foil pouch	(moisture barrier) and a secondary outer Tyvek pouch (sterile barrier).	

Non-Clinical and/or Clinical Tests Summary

Performance/Non-Clinical Testing

The following performance and non-clinical testing were performed to demonstrate substantial equivalence:

Test Description	Standard
Sterilization Validation	ISO 11135
Stability/Shelf-Life Testing	ASTM F1980-21, ASTM F88/F88M, ISO 10993-5, USP43-NF38 2S, ASTM F88/F88M, ASTM D3078-02, F1886/F1886M-16
Biocompatibility Assessment	ISO 10993-1; ISO 10993-3; ISO 10993-5; ISO 10993-6
Packaging Validation	ASTM F1980-21, ISO 11607-1, ASTM F88/F88M, ASTM D4169-23E01, ASTM D3078-02, F1886/F1886M-16
Benchtop Performance Testing • Needle Attachment Force • USP Suture Diameter • Tensile Knot Pull Strength • Foil Pouch Peel Strength • Visual Inspection • Suture Length • Suture Removal Force	 • USP <871> • USP <861> • USP <881> • ASTM F88/F88M • ANSI/ASQ Z1.4 (for AQL sampling • USP-NF Absorbable Surgical Suture • N/A

Biocompatibility endpoints tested: Cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, implantation.

Chemical Characterization and Toxicological Risk assessment (CC/TRA) was used to evaluate systemic toxicity, genotoxicity, carcinogenicity, and reproductive/developmental toxicity.

No clinical testing was required.

Conclusion:

Based upon the supporting data summarized above, Trexon™ Monofilament Synthetics Absorbable Suture is as safe and effective, and therefore substantially equivalent to the legally marketed predicate device, Biosyn™ Monofilament Synthetics Absorbable Suture (K000037).