March 30, 2020

Teleflex Medical
Robin Haden
Regulatory Affairs Specialist
3015 Carrington Mill Blvd
Morrisville, North Carolina 27560

Re: K192490
Trade/Device Name: Tevdek II, "Silky" II Polydek, 'Cottony' II, NextStitch
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: February 21, 2020
Received: February 24, 2020

Dear Ms. Haden:

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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192490

Device Name
"silky" II POLYDEK®, 'cottony' II, TEVDEK® II Polyester Surgical Suture

Indications for Use *(Describe)*
Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.

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.

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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)*
K192490

Device Name
'cottony' II Polyester Surgical Suture Tape

Indications for Use *(Describe)*
Polyester Surgical Suture Tapes are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.

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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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)*
K192490

Device Name
TEVDEK® II NextStitch® and "silky" II POLYDEK® NextStitch® Cardiovascular Valve Suture

Indications for Use *(Describe)*
TEVDEK® II NextStitch® and 'silky' II POLYDEK® NextStitch® cardiovascular valve suture are indicated for use for soft tissue approximation and/or ligation in cardiovascular valve replacement procedures.

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) SUMMARY

Deknatel® Polyester Surgical Suture

A. Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560

Phone: 919-544-8000
Fax: 919-433-3914

B. Contact Person

Robin Haden
Surgical Business Unit
Tel – (919) 433-8046
Fax – (919) 433-3914
Email – robin.haden@teleflex.com

C. Date Prepared

March 18, 2020

D. Device Name

Trade Name(s)	Deknatel® Polyester Surgical Sutures, including: – "silky" II POLYDEK® Polyester Surgical Suture – 'cottony' II Polyester Surgical Suture and Tape – TEVDEK® II Polyester Surgical Suture – TEVDEK® II NextStitch® Cardiovascular Valve Suture – "silky" II POLYDEK® NextStitch® Cardiovascular Valve Suture
Product Code	GAT (Suture, Nonabsorbable, Synthetic, Polyethylene)
Regulation	21 CFR 878.5000
Classification Name	Nonabsorbable poly(ethylene terephthalate) surgical suture

E. Device Description

The Deknatel® Polyester Surgical Suture is a non-absorbable surgical suture composed of twisted or braided Polyethylene Terephthalate fibers. Deknatel® Polyester Surgical Suture is available undyed (white) or dyed (green) and is offered in a variety of cut lengths, with or without needles, and with or without pledgets. Product labeling carries the following specific information on the suture: material (including color, number and length of sutures in the package); USP size (diameter, including any difference in diameter); the number, profile and size of any attached needles; and the number, size and density of pre-attached pledgets.

The Deknatel® Polyester Surgical Suture meets all nonabsorbable surgical suture requirements established by the United States Pharmacopeia (USP) for tensile strength, diameter and needle attachment, except for suture size 7-0 which differs from USP in diameter only.

Deknatel® Polyester Surgical Suture is available in USP sizes 7-0 to 9 in the following configurations:

- 'cottony' II: Uncoated (Not PTFE impregnated)
- "silky II" or Polydek®: Lightly coated (PTFE impregnated)
- Tevdek® II: Heavily coated (more PTFE impregnated than "silky"))

The Deknatel® Polyester Surgical Sutures are also available in the following product-specific configurations with or without needles, and with or without pledgets:

- Surgical Suture Tape as uncoated 'cottony' II in flat braid sizes of 1/8", 1mm, 2 mm, 3mm, 4mm and 5mm.
- NextStitch® Cardiovascular Valve Suture is comprised of "silky" II POLYDEK and/or TEVDEK II polyester suture. NextStitch is a continuous chain of linked sutures designed to provide an alternative suturing technique for cardiovascular valve replacement procedures. NextStitch Sutures are available in USP Sizes 4-0, 3-0, 2-0 and 0 (metric sizes 1.5 through 3.5).
- Readi-Cut TEVDEK® II Bulk Non-Sterile Polyester Surgical Suture is bulk, non-sterile Tevdek® II polyester suture available in USP Size 2.

F. Indications for Use and Contraindications

Sterile Deknatel® Polyester Suture, previously cleared under K153076 and K153089, carries the following indications and contraindications:

"silky" II POLYDEK®, 'cottony' II, TEVDEK® II Polyester Surgical Suture and Tape

Indications:

Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.

Contraindications:
None known.

TEVDEK® II NextStitch® and "silky" II POLYDEK® NextStitch® Cardiovascular Valve Suture

Indications:
TEVDEK II NextStitch and "silky" II POLYDEK NextStitch cardiovascular valve suture are indicated for use for soft tissue approximation and/or ligation in cardiovascular valve replacement procedures.

Contraindications:
None known.

Non-sterile Deknatel® Polyester Suture, previously cleared under K930739, carries the following indications and contraindications:

READI-CUT TEVDEK® II Non-Sterile Polyester Surgical Suture

Indications:
Deknatel Polyester Surgical Sutures (i.e. Dacron®, Polydek, and Tevdek) are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.

Contraindications:
None known.

G. Substantial Equivalence

The proposed Deknatel Polyester Surgical Suture is substantially equivalent to the predicate devices cleared below:

Predicate Device	Manufacturer	510(k)	Clearance Date
"silky" II POLYDEK, 'cottony' II, TEVDEK II, NextStitch, DEKLENE II, DEKLENE MAXX Gabbay-Frater, NYLON, SILK, STAINLESS STEEL	Teleflex Medical, Inc.	K153076	June 16, 2016
'cottony' II Polyester Suture Tape	Teleflex Medical, Inc.	K153089	July 15, 2016

The following reference device information is included to support the inclusion of the non-sterile Deknatel® Polyester Surgical Suture. The proposed non-sterile device is substantially equivalent to the reference non-sterile Deknatel® Polyester Surgical Suture cleared below:

Reference Device	Manufacturer	510(k)	Clearance Date
SUTURES POLYPROP., POLYETHYLENE, NYLON & SILK	Teleflex Medical, Inc.	K930739	July 26, 1994

H. Comparison To Predicate Devices

The proposed sterile Deknatel® Polyester Surgical Suture is substantially equivalent in intended use and fundamental scientific technology to the Deknatel® Polyester Surgical Suture predicate devices cleared under K153076 on June 16, 2016 and K153089 on July 15, 2016. The proposed non-sterile Deknatel® Polyester Surgical Suture is substantially equivalent in intended use and fundamental scientific technology to the non-sterile Deknatel® Polyester Surgical Suture devices cleared under reference K930739 on July 26, 1994. Nonclinical testing on functionality, stability, biocompatibility, and MR safety was conducted to confirm that the supplier changes did not negatively impact device performance. The testing results concluded that the only difference between the subject and predicate sutures are the sources for the PET resin and the PTFE impregnation/dispersion coating materials.

The following tables contain the technological characteristics of the proposed devices in comparison to the predicate and reference devices.

Substantial Equivalence Summary Table (Sterile Product)

Comparative Characteristics	**Predicate Device**	**Proposed Device**	**Explanation of Differences**
Manufacturer	Teleflex Medical		Identical
510(k) Number	K153076, K153089	K192490	N/A
Product Code	GAT		Identical
Regulation	878.5000		Identical
Device Class	2		Identical
Indications for Use ('cottony' II, "silky" II POLYDEK, TEVDEK II Sutures)	Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.		Identical

Comparative Characteristics	Predicate Device	Proposed Device	Explanation of Differences
Indications for Use ('cottony' II Suture Tapes)	Polyester Surgical Suture Tapes are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.		Identical
Indications for Use (NextStitch)	TEVDEK II NextStitch and "silky" II POLYDEK NextStitch cardiovascular valve suture are indicated for use for soft tissue approximation and/or ligation in cardiovascular valve replacement procedures.		Identical
Contraindications	None known.		Identical
Trade Names	"silky" II POLYDEK® 'cottony' II, TEVDEK® II, NextStitch®		Identical
USP Size ('cottony' II, "silky" II POLYDEK, TEVDEK II)	9-0 to 9	7-0 to 9	Equivalent, *within cleared size range*
USP Size (NextStitch)	4-0 to 0		Equivalent
Size 'cottony II' Suture Tape	1/8", 1mm, 2mm, 3mm, 4mm, 5mm		Equivalent
Suture Diameter	All sizes meet USP <861> requirements for nonabsorbable surgical suture except tape which does not conform to USP Diameter		Identical
Suture Tensile Strength	All sizes meet USP <881> requirements for nonabsorbable surgical suture		Identical
Needle Attachment Strength	All sizes meet USP <871> requirements for nonabsorbable surgical suture		Identical
Material	Polyester [Poly(ethylene terephthalate)]		Identical
Suture Construction	Braided		Identical
Impregnated/Coated	Yes ("silky" II POLYDEK or TEVDEK II) with Polytetrafluoroethylene		Identical
Uncoated	Yes ('cottony' II)		Identical
Undyed White	Yes		Identical
D&C Green No. 6	Yes		Identical
Co-braid (White/Green)	Yes		Identical
Impregnated	Yes		Identical

Comparative Characteristics	Predicate Device	Proposed Device	Explanation of Differences
PTFE Pledget			
Pledget Material	polytetrafluoroethylene (PTFE)		Identical
Needle Material	300 or 400 Series Stainless Steel		Identical
Package Materials	Solid Sulfite Board (SBS)/ Uncoated Tyvek Pouch		Identical
Sterility Method	Ethylene Oxide (EO); SAL 10^{-6}		Identical
Biocompatibility	Per ISO 10993-1		Identical
Shelf Life	5 Years		Identical

Substantial Equivalence Summary Table (Non-Sterile Product)

Comparative Characteristics	Reference Device	Proposed Device	Explanation of Differences
Manufacturer	Teleflex Medical	Teleflex Medical	Identical
510(k) Number	K930709	K192490	N/A
Product Code	GAT		Identical
Regulation	878.5000		Identical
Device Class	2		Identical
Indications for Use TEVDEK® II	Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures.		Identical
Contraindications	None known.		Identical
Trade Names	TEVDEK® II		Identical
USP Size TEVDEK®	2		Identical
Suture Diameter	All sizes meet USP <861> requirements for nonabsorbable surgical suture except tape which does not conform to USP Diameter		Identical
Suture Tensile Strength	All sizes meet USP <881> requirements for nonabsorbable surgical suture		Identical
Needle Attachment Strength	All sizes meet USP <871> requirements for nonabsorbable surgical suture		Identical
Material	Polyester [Poly(ethylene terephthalate)]		Identical
Suture Construction	Braided		Identical
Impregnated/Coated	Polytetrafluoroethylene		Identical
D&C Green No. 6	Yes		Identical
Package Materials	Solid Sulfite Board (SBS)/ Uncoated Tyvek Pouch		Identical
Sterility Method	N/A- Sold Non-Sterile		Identical

Comparative Characteristics	Reference Device	Proposed Device	Explanation of Differences
Biocompatibility	Per ISO 10993-1		Identical
Shelf Life	N/A- Sold Non-Sterile		Identical

I. Materials

All patient contacting materials are in compliance with ISO10993-1. The proposed modification is replacing the source of the polyester resin and polytetrafluoroethylene (PTFE) coating used to manufacture the Deknatel® Polyester Surgical Sutures.

J. Technological Characteristics

A comparison of the technological characteristics of the proposed Deknatel® Polyester Surgical Suture and the predicate has been performed. The results of this comparison demonstrate that the Deknatel Polyester Surgical Sutures are equivalent to the marketed predicate devices in performance, stability, biocompatibility and MR safety characteristics.

K. Performance Data

Non-clinical testing has been conducted in accordance with *USP (United States Pharmacopeia) 40-NF 35 <861> Sutures – Diameter, <871> Sutures- Needle Attachment, and <881>Tensile Strength* in order to verify the new polyester suture resin and polytetrafluoroethylene (PTFE) coating of the proposed Deknatel Polyester Surgical Sutures are substantially equivalent to the predicate devices in performance Additional non-clinical testing was conducted to confirm substantial equivalence with regards to stability, MR safety and biocompatibility (per ISO 10993-1).

L. Conclusion

Based upon the comparative test results, the proposed Deknatel Polyester Surgical Sutures are substantially equivalent in performance, stability, biocompatibility and MR safety to the predicate devices cleared to market via 510(k)s K153076, K153089, and reference 510(k) K930739. The proposed new sources of polyester resin and PTFE coating are the only changes to the product and do not introduce any new issues of safety and effectiveness.