



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

June 16, 2016

Teleflex Medical, Inc.  
Ms. Natalie Hichak  
Sr. Regulatory Affairs Specialist  
3015 Carrington Mill Blvd.  
Morrisville, NC 27560

Re: K153076

Trade/Device Name: "silky" II POLYDEK, "cottony" II, TEVDEK II, NextStitch,  
DEKLENE II, DEKLENE MAXX Gabbay-Frater, NYLON, SILK,  
STAINLESS STEEL

Regulation Number: 21 CFR 878.5000

Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture

Regulatory Class: Class II

Product Code: GAT

Dated: May 18, 2016

Received: May 19, 2016

Dear Ms. Hichak:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**David Krause -S**

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)  
K153076

Device Name

'silky' II POLYDEK®, 'cottony'™ II, TEVDEK® II, NextStitch® Cardiovascular Valve Suture, DEKLENE® II, DEKLENE® MAXX™, NYLON Surgical Suture, SILK Surgical Suture, STERMOTOMY STAINLESS STEEL Suture,

Indications for Use (Describe)

NextStitch® cardiovascular valve suture are indicated for use for soft tissue approximation and/or ligation in cardiovascular valve replacement procedures.

Polypropylene Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, and neurological procedures, but not for use in ophthalmic procedures.

Nylon Surgical Suture is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, and neurological procedures.

SILK Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Stainless Steel Sutures are indicated for use in abdominal wound closure, hernia repair, sternal closure, and orthopedic procedures, including cerclage and tendon repair.

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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## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

### Deknatel® Nonabsorbable Surgical Sutures

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

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

Phone: 919-433-8049  
Fax: 919-433-4996

#### B. Contact Person

Natalie Hichak  
Sr. Regulatory Affairs Specialist

#### C. Date Prepared

July 10, 2015

#### D. Device Name

<b>Trade Name</b>	'silky' II POLYDEK®, 'cottony'™ II, TEVDEK® II Polyester Surgical Sutures
<b>Common Name</b>	Suture, Nonabsorbable, Synthetic, Polyethylene
<b>Classification Name</b>	Nonabsorbable poly(ethylene terephthalate) Surgical Suture
<b>Trade Name</b>	NextStitch® Cardiovascular Valve Suture
<b>Common Name</b>	Suture, Nonabsorbable, Synthetic, Polyethylene
<b>Classification Name</b>	Nonabsorbable poly(ethylene terephthalate) Surgical Suture
<b>Trade Name</b>	DEKLENE® II, DEKLENE® MAXX™
<b>Common Name</b>	Polypropylene Surgical Suture Suture, Nonabsorbable, Synthetic, Polypropylene
<b>Classification Name</b>	Nonabsorbable, Synthetic, Polypropylene
<b>Trade Name</b>	NYLON Surgical Suture
<b>Common Name</b>	Suture, Nonabsorbable, Synthetic Polyamide
<b>Classification Name</b>	Suture, Nonabsorbable, Synthetic, Polyamide

**Trade Name** SILK Surgical Suture  
**Common Name** Suture, Nonabsorbable, Silk  
**Classification Name** Natural Nonabsorbable Silk Surgical Suture

**Trade Name** STERMOTOMY STAINLESS STEEL Suture  
**Common Name** Suture, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile  
**Classification Name** Stainless Steel Suture

**Trade Name** Gabbay-Frater™ Suture Guide  
**Common Name** Guide, Surgical, Instrument  
**Classification Name** Manual Surgical Instrument for General Use

## E. Device Description

Deknatel Nonabsorbable Surgical Sutures are available in five (5) different material options.

1. Poly(ethylene terephthalate) a polyester fiber.
  - The three types of polyester sutures are ‘cottony’™ II, ‘silky’ II POLYDEK, and TEVDEK II. ‘cottony’ II is uncoated polyester suture. ‘silky’ II POLYDEK® suture has a light coating of Polytetrafluoroethylene (PTFE) and TEVDEK II has a heavy PTFE coating.
  - NextStitch Cardiovascular Valve Suture is a combination 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.
2. Polypropylene: DEKLENE II and DEKLENE® MAXX are the two varieties of this material.
3. NYLON is composed of monofilament synthetic polyamide fiber.
4. SILK is composed of grade 4A Chinese silk derived from the domesticated species *Bombyx mori* (B mori) of the family Bombycidae.
5. STERNOTOMY STAINLESS STEEL sutures are composed of 316 LVM stainless steel.

All sutures are provided in a variety of lengths, with and without needles, and (if applicable) with and without pre-attached pledgets (if applicable).

An accessory that can be used with the Nonabsorbable Surgical Sutures is the Gabbay-Frater Suture Guide which is a convenient suture organizer which keeps suture ends tangle-free.

**F. Indications for Use and Contraindications**

<b>Trade Name</b>	'silky' II POLYDEK®, 'cottony'™ II, TEVDEK® II Polyester Surgical Sutures
<b>Indications for Use</b>	Polyester Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, orthopedic and neurological procedures.
<b>Contraindication</b>	None known.
<b>Trade Name</b>	NextStitch® Cardiovascular Valve Suture TEVDEK® II NextStitch® and "silky" II POLYDEK®
<b>Indications for Use</b>	NextStitch® cardiovascular valve suture are indicated for use for soft tissue approximation and/or ligation in cardiovascular valve replacement procedures.
<b>Contraindication</b>	None known.
<b>Trade Name</b>	DEKLENE® II, DEKLENE® MAXX™ Polypropylene Surgical Suture
<b>Indications for Use</b>	DEKLENE® II and DEKLENE® MAXX™ Polypropylene Surgical Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, and neurological procedures, but not for use in ophthalmic procedures.
<b>Contraindication</b>	None known.
<b>Trade Name</b>	NYLON Surgical Suture
<b>Indications for Use</b>	Nylon Surgical Suture is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, and neurological procedures.
<b>Contraindication</b>	Due to the gradual loss of tensile strength which may occur over prolonged periods in vivo, Nylon Sutures should not be used where permanent retention of tensile strength is required.
<b>Trade Name</b>	SILK Surgical Suture
<b>Indications for Use</b>	SILK Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.
<b>Contraindication</b>	The use of this suture is contraindicated in patients with known sensitivities or allergies to silk. Due to the gradual loss of tensile strength which may occur over prolonged periods <u>in vivo</u> , Silk Suture should not be used where permanent retention of tensile strength is required.

**Trade Name** STERMOTOMY STAINLESS STEEL Suture  
**Indications for Use** Stainless Steel Sutures are indicated for use in abdominal wound closure, hernia repair, sternal closure, and orthopedic procedures, including cerclage and tendon repair.  
**Contraindication** The use of these sutures is contraindicated in patients with known sensitivities or allergies to the metals contained in 316LVM stainless steel, i.e., chromium, nickel, copper, cobalt, and iron.

**Trade Name** Gabbay-Frater™ Suture Guide  
**Indications for Use** Gabbay-Frater™ is a device for organizing, arranging and counting multiple interrupted sutures in an orderly fashion.  
**Contraindication** None known.

## G. Substantial Equivalence

The proposed Deknatel Nonabsorbable Surgical Sutures is substantially equivalent to the predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
COTTONY' II, "silky" II POLYDEK® & TEVDEK® II Polyester Nonabsorbable Surgical Suture	Genzyme Corp	K021019	June 18, 2002
Nextstitch™ Cardiovascular Valve Suture	Genzyme Surgical Product (Genzyme Biosurgery)	K001440	November 13, 2000
Deknatel™ Bondek® Polyglycolic Acid Synthetic Absorbable Surgical Suture, Deknatel™ Plain and Chromic Gut Surgical Suture, Deknatel™ II Surgical Suture, Deknatel™ OpthaMend™ Ophthalmic Polypropylene Surgical Suture, Deknatel™ 'Cottony' II Dacron® Surgical Suture, Deknatel™ 'Silky' II Polydek® Surgical Suture, Deknatel™ Tevdek® II Surgical Suture, Deknatel™ Nylon Surgical Suture, Deknatel™ Silk Surgical Suture, and Deknatel™ Stainless Steel Surgical Suture	Deknatel, Inc	K930738	July 25, 1994
Gabbay-Frater™ Suture Guide	Howmedica Corp	K802093	September 26, 1980

## **H. Comparison To Predicate Devices**

The proposed Deknatel Nonabsorbable Surgical Sutures have the same technology, indications for use and functional characteristics as the predicate system. The proposed modification is to add a stability claim of 5 years and to transfer the ownership from Genzyme to Teleflex Medical.

## **I. Materials**

All patient contacting materials are in compliance with ISO10993-1.

## **J. Technological Characteristics**

A comparison of the technological characteristics of the proposed Deknatel Nonabsorbable Surgical Sutures and the predicate has been performed. The results of this comparison demonstrate that the Nonabsorbable Surgical Sutures are equivalent to the marketed predicate devices in performance characteristics.

## **K. Performance Data**

Non-clinical real-time aging testing has been performed in accordance with ISO11607-1:2006, *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* and USP (*United States Pharmacopeia*) 36-NF 31 <861> *Sutures – Diameter*, <871> *Sutures- Needle Attachment*, and <881> *Tensile Strength* in order to verify addition of a 5 year shelf-life of the proposed Deknatel Nonabsorbable Surgical Sutures are substantially equivalent to the predicate devices.

## **L. Conclusion**

Based upon the comparative test results, the proposed Deknatel Nonabsorbable Surgical Sutures are substantially equivalent in performance to the predicate devices cleared to market via 510(k)s K021019, K001440, K930738 and K802093.