DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 23, 2016

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

Re: K162396
Trade/Device Name: Silk Surgical Suture
Regulation Number: 21 CFR 878.5030
Regulation Name: Natural Nonabsorbable Silk Surgical Suture
Regulatory Class: Class II
Product Code: GAP
Dated: August 24, 2016
Received: August 26, 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" (21 CFR 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162396

Device Name
Deknatel® Silk Surgical Sutures

Indications for Use *(Describe)*
Deknatel® Silk Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic 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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510(k) SUMMARY

Deknatel® Silk Surgical Sutures

I. SUBMITTER

Teleflex Medical, Inc.
3015 Carrington Mill Blvd
Morrisville, NC 27560
Phone: 919-433-8049
Fax: 919-433-4996

Contact Person: Natalie Hichak, Senior Regulatory Affairs Specialist
Date Prepared: August 24, 2016

II. DEVICE

Name of Device	Deknatel Silk Surgical Suture
Common Name	Suture, Nonabsorbable, Silk
Classification Name	Natural Nonabsorbable Silk Surgical Suture
Regulatory Class	II
Product Code	GAP
Regulation	878.5030

III. PREDICATE DEVICE

Deknatel® Nonabsorbable Surgical Sutures, K153076

IV. DEVICE DESCRIPTION

Deknatel Silk Suture is a nonabsorbable, sterile, surgical suture composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. Silk Suture is waxed, braided or twisted, and provided dyed (black) or undyed (natural white).

Silk Suture meets all requirements established by the United States Pharmacopeia (USP) for Nonabsorbable Surgical Suture and is available in USP sizes 10-0 through 5 (metric sizes 0.2 through 7). The suture is supplied sterile, waxed, and braided or twisted. The suture is provided in a variety of lengths, with and without needles, with and without pledgets, and may be supplied in a variety of cut lengths or on ligating reels. Finished suture may be packaged in cartons as single packs, multipacks or procedure packs.

V. INDICATIONS FOR USE

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

The Indications for Use statement for Deknatel Silk Surgical Sutures is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed Deknatel Silk Surgical Sutures have the same technology, indications for use and functional characteristics as the predicate system. The proposed modification is a dying process change to replace the current mordant, Sodium Dichromate with Ferrous Sulfate.

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

VII. PERFORMANCE DATA

Non-clinical testing has been performed in accordance *USP (United States Pharmacopeia) Nonabsorbable Sutures, 36-NF 31 <861> Sutures – Diameter, <871> Sutures- Needle Attachment, and <881>Tensile Strength* in order to verify mordant material change of the proposed Deknatel Silk Surgical Sutures are substantially equivalent to the predicate devices.

Biocompatibility Testing

The biocompatibility evaluation for the Deknatel Silk Surgical Suture was conducted in accordance with FDA Blue Book Memorandum #G95-1 "Use of International Standards ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standards ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by the FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Subchronic toxicity
- Genotoxicity
- Implantation
- Haemocompatibility
- Pyrogen testing

The Deknatel Silk Surgical Sutures is considered a permanent implant (> 30 days) and the nature of body contact is tissue/bone and blood. Deknatel Silk

Suture is composed of an organic protein called fibroin. This protein is derived from the domesticated species Bombyx mori (B. mori) of the family Bombycidae. Silk Suture is waxed with beeswax or a beeswax and paraffin mixture. Black silk suture is dyed with Logwood dye.

VII. CONCLUSIONS

Based upon the comparative test results, the proposed Deknatel Silk Surgical Sutures are substantially equivalent in performance to the predicate devices cleared to market via 510(k)s K153076.