March 19, 2020

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

Re: K193530
Trade/Device Name: Deklene MAXX
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: December 19, 2019
Received: December 20, 2019

Dear Robin 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)*
K193530

Device Name
Deknatel® Deklene® MAXX™ Polypropylene Surgical Suture

Indications for Use *(Describe)*
Deknatel® 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.

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.

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510(K) Summary

Submission Date: 12/20/2019
K193530

SUBMITTER INFORMATION:

Company Name: Teleflex Medical, Inc.

Company Address: 3015 Carrington Mill Blvd, Morrisville, NC 27560

Contact Person: Robin Haden
Phone: 919-544-8000
robin.haden@teleflex.com

Device Trade Name: Deknatel® Deklene® Maxx™ Polypropylene Surgical Suture

Device Common Name: Polypropylene nonabsorbable surgical suture

Class: Class II

Classification: 21 CFR 878.5010

Product Code: GAW

Predicate Devices:

The predicate is Deknatel® Deklene® Maxx™ Polypropylene Suture devices cleared under K930738 (July 26, 1994) and K153076 (June 16, 2016).

Device Description:

Deknatel® Deklene® Maxx™ Polypropylene Suture is a nonabsorbable, sterile surgical suture composed of a strand of polypropylene, a synthetic linear polyolefin. Deknatel® Deklene® MAXX™ Polypropylene Surgical Suture is available dyed (blue) or undyed (colorless).

Deknatel® Deklene® Maxx™ Polypropylene Surgical Suture meets all nonabsorbable surgical suture requirements established by the United States Pharmacopeia (USP) except for suture sizes 7-0 and 8-0 which differ from USP in diameter only.

Deknatel® Deklene® Maxx™ Polypropylene Surgical Suture is available in USP sizes 8-0 through 0. The suture is provided in a variety of lengths, with and without 300 or 400 series stainless steel needles, with and without PTFE felt pledgets, and may be supplied in a variety of cut lengths. Finished suture may be packaged in cartons as single packs, multipacks or procedure packs.

Intended Use:

Deknatel® 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.

Technological Characteristics

The proposed Deknatel® Deklene® Maxx™ Polypropylene Suture is substantially equivalent to its predicate Deknatel® Deklene® Maxx™ Polypropylene Suture devices because there are no differences in technological or performance characteristics between the proposed and predicate devices. The difference between the proposed device and the predicate device is the supplier from which the resin used for extrusion is acquired. The resin from the new supplier is equivalent to that from the current supplier and does not introduce any new issues of safety and effectiveness. The results of the comparison between the technological characteristics of Deknatel® Deklene® Maxx™ Polypropylene Suture manufactured with the proposed and predicate material demonstrate that the proposed Deknatel® Deklene® Maxx™ Polypropylene Sutures are equivalent to the marketed predicate devices in performance characteristics.

Materials

All patient contacting materials are in compliance with the requirements of ISO 10993-1. The proposed modification is replacing the source of the polypropylene resin used to manufacture the Deknatel® Deklene® Maxx™ Polypropylene Suture.

Summary of Testing

Deknatel® Deklene® Maxx™ Polypropylene Suture is tested in accordance with the requirements of USP – non-absorbable surgical sutures for suture diameter, , tensile strength and needle attachment, and meet the requirements of Class II Special Controls Guidance: Surgical Sutures; Guidance for Industry and FDA; June 3, 2003.

All materials used in the fabrication of the Deknatel® Deklene® Maxx™ Polypropylene Suture were evaluated through biological qualification safety tests as outlined in ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part I: Evaluation and Testing.

Deknatel® Deklene® Maxx™ Polypropylene Suture is tested to demonstrate it is “MR Safe” and poses no hazards in an MR environment with any needles removed.

Substantial Equivalence:

The proposed Deknatel® Deklene® Maxx™ Polypropylene Surgical Suture is substantially equivalent in intended use and fundamental scientific technology to the Deknatel® Deklene® Maxx™ Polypropylene Suture devices cleared under K930738 (July 26, 1994) and K153076 (June 16, 2016). The substantial equivalence table for the comparison of the previously cleared devices and the proposed devices is included in the Table below.

Comparative Characteristics	Predicate Device (K153076, K930738)	Proposed Device	Explanation of Differences
Manufacturer	Teleflex Medical		Identical
Product Code	GAW		Identical
Regulation	878.5010		Identical
Device Class	2		Identical
Indications for Use	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.		Identical
Contraindications	None known.		Identical
Trade Names	Deklene® Maxx™		Identical
Deklene® Maxx™ USP Size	8-0 to 2	8-0 to 0	*Equivalent within stated range*
Suture Diameter	All sizes except 7-0 and 8-0 meet USP <861> requirements for nonabsorbable surgical suture		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	Polypropylene (synthetic linear polyolefin)		Identical
Suture Construction	Monofilament		Identical
Coated	No		Identical
Uncoated	Yes		Identical
Undyed White	Yes		Identical
Dyed Blue with [phthalocyaninato(2-)] copper	Yes		Identical
Impregnated PTFE Pledget	Yes		Identical
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

Clinical Tests Performed:

No clinical trials were conducted

Conclusion:

The proposed Deknatel® Deklene® Maxx™ Polypropylene Suture is substantially equivalent to its predicate Deknatel® Deklene® Maxx™ Polypropylene Suture devices because there are no differences in technological or performance characteristics between the proposed and predicate devices.

The proposed modification is replacing the source of the polypropylene resin used to manufacture the Deknatel® Deklene® Maxx™ Polypropylene Suture. It also has the same design being a sterile, flexible, monofilament nonabsorbable thread meeting the requirements of the United States Pharmacopeia.

The biocompatibility data and the results of performance testing presented, demonstrate the substantial equivalence of Deknatel® Deklene® Maxx™ Polypropylene Suture to that of the predicate devices. It further demonstrates conformance with the USP, ISO 10993 and FDA Guidance for Surgical Suture 510(k).

The new device Deknatel® Deklene® MAXX™ Polypropylene Surgical Suture is substantially equivalent in intended use and fundamental scientific technology to the predicate devices Deknatel® Deklene® Maxx™ Polypropylene Suture cleared under K930738 and K153076.