July 31, 2019

DemeTECH Corporation
Tracy Chadwrick
Director of Quality
14175 NW 60th Ave
Miami Lakes, Florida 33014

Re: K190777
Trade/Device Name: DemeTECH DemeFORCE Nonabsorbable Surgical Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: April 29, 2019
Received: April 29, 2019

Dear Tracy Chadwrick:

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,

For Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Assistant Director (Acting), Plastic Surgery Implant Devices Team
Division of Infection Control and Plastic Surgery Devices
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)*
K190777

Device Name
DemeTECH DemeFORCE Nonabsorbable Surgical Suture

Indications for Use *(Describe)*
DemeFORCE Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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005 – 510K Summary

This summary is submitted in accordance with the Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR § 807.92. This summary demonstrates the equivalence of Demetech Sutures to those of the legally marked devices listed.

A. Applicant:

Demetech Corporation,
14175 NW 60th Ave.
Miami Lakes FL. 33014

B. Contact Person:

Tracy Chadwrick
Phone: 305-824-1048
tracy.chadwrick@demetech.us

C. Date Summary Prepared: February 07, 2019

Trade Name: DemeTECH DemeFORCE Surgical Suture

Common Name: Ultra-high-molecular-weight polyethylene (UHMWPE) Nonabsorbable Surgical Suture

Classification Name: Non-absorbable poly(ethylene terephthalate) surgical suture

Product Code: GAT
21 CFR 878.5000
Class II

D. Predicate Devices: The DemeTECH UHMWPE Suture is substantially equivalent to the predicates Arthrex (UHMWPE) and Force Fiber OrthoTape Nonabsorbable Suture in which the basic features and intended uses are the same. Any differences between the DemeTECH UHMWPE Suture and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

- Teleflex Medical Incorporated, Force Fiber® OrthoTape™ reference 510k number K150438
- Arthrex Incorporation, Arthrex (UHMWPE) reference 510k number K122374

E. Device Description:

DemeTECH DemeFORCE Suture is a nonabsorbable, sterile surgical monofilament suture composed of Ultra-high-molecular-weight polyethylene. The DemeTECH UHMWPE Suture meets or exceeds all requirements in the latest edition of the USP monograph for nonabsorbable surgical sutures and is provided sterile in various sizes and configurations. The material is available in different colors and may be provided with or without an attached needle(s).

F. Intended Use:

DemeFORCE Suture is indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries

G. Non-Clinical Tests Performed:

Non-clinical testing was conducted on the device per FDA's Special Control Guidance Document: Surgical Sutures, to prove conformance to the requirements of USP for synthetic absorbable suture, biocompatibility testing in accordance to ISO 10993-1 and in-vitro and in-vivo resorption to further demonstrate substantial equivalence to the predicate devices. Physical properties and functionality testing assured that the device conformed with suture diameter, suture length, knot pull tensile strength, needle attachment strength, extractable color and sterility to methods outlined in USP 41.

COMPARISON TABLE			
Comparison Items	Demetech DemeFORCE Nonabsorbable Suture	Force Fiber®OrthoTape™ Nonabsorbable Suture	Arthrex (UHMWPE) Nonabsorbable Suture
Product Code	GAT	GAT	GAT
Common Name	UHMWPE and Polyester Nonabsorbable suture	UHMWPE and Polyester Nonabsorbable suture	UHMWPE and Polyester Nonabsorbable suture
Suture Characteristic	Nonabsorbable multicolor co-braid of UHMWPE and Polyester surgical suture	Nonabsorbable multicolor co-braid of UHMWPE and other materials surgical suture	Nonabsorbable multicolor co-braid of UHMWPE and other materials surgical suture
Labeling	Sterile, Single Use	Sterile, Single Use	Sterile, Single Use
Intended Use	Approximation or ligation of soft tissues	Same, does not include exclusions in indications statement.	Same, also includes cardiovascular as well as repair of the dura mater.
Technical Characteristics	USP Nonabsorbable suture	USP Nonabsorbable suture	USP Nonabsorbable suture
Material	UHMWPE and Polyester (UHMWPE)	UHMWPE alone or with Polyester, nylon 6,6 or polypropylene (UHMWPE)	UHMWPE and Polyester (UHMWPE)
Sizes	7, 6, 5, 4, 3, 2, 1, 0, 1-0, 2-0	6, 5, 4, 3, 2, 1, 0, 1-0, 2-0	6, 5, 4, 3, 2, 1, 0, 1-0, 2-0
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)

USP Performance Requirements	Suture Material meets or exceeds performance requirements for "Nonabsorbable Surgical Suture" in USP 41.	Suture Material meets or exceeds performance requirements for "Nonabsorbable Surgical Suture" in USP 41.	Suture Material meets or exceeds performance requirements for "Nonabsorbable Surgical Suture" in USP 41.
Tensile Strength Requirements	Suture Material meets or exceeds the performance requirements defined in USP for "Tensile Strength" < 881 >	Suture Material meets or exceeds the performance requirements defined in USP for "Tensile Strength" < 881 >	Suture Material meets or exceeds the performance requirements defined in USP for "Tensile Strength" < 881 >
Needle Attachment Requirements	Suture Material meets or exceeds the performance requirements defined in USP for "Needle Attachment" < 871 >	Suture Material meets or exceeds the performance requirements defined in USP for "Needle Attachment" < 871 >	Suture Material meets or exceeds the performance requirements defined in USP for "Needle Attachment" < 871 >
Suture Length Requirements	Suture Material meets or exceeds the performance requirements defined in USP for "Suture Length Requirement" (95% of stated label length)	Suture Material meets or exceeds the performance requirements defined in USP for "Suture Length Requirement" (95% of stated label length)	Suture Material meets or exceeds the performance requirements defined in USP for "Suture Length Requirement" (95% of stated label length)
Suture Packaging	Device wound onto inner support card, within a Tyvek / Poly pouch	Device wound onto inner support card, within a Tyvek/Poly Primary Pouch; inside a Tyvek / Poly secondary pouch	Device wound onto inner support card, within a Tyvek / Poly pouch

H. Clinical Tests Performed:

No clinical trials were conducted

I. Conclusion:

DemeTECH DemeFORCE Nonabsorbable Surgical Suture is composed of the same material as are the predicated devices and the same design' being a sterile, flexible, threads meeting the requirements of the United States Pharmacopeia. DemeTECH DemeFORCE Surgical Suture is manufactured in the same manner as the predicate devices in operations considered standard in the fiber industry forming the finished suture fiber in bulk. The manufacturer supplies these bulk fibers to DemeTECH with the same materials as it sells to other suture manufacturers including those with cleared 510K submissions.

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

Based on the 510(k) summaries and the information provided herein we conclude that DemeTECH DemeFORCE Nonabsorbable Surgical Suture is substantially equivalent and as safe and effective as the predicate device.