November 7, 2019

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

Re: K191361
Trade/Device Name: DemeDIOX Barbed Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: May 10, 2019
Received: May 21, 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,

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)*
K191361

Device Name
DemeDIOX Barbed Absorbable Surgical Suture

Indications for Use *(Describe)*
DemeDIOX Barbed polydioxanone suture is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

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

Submission Date: 11/07/2019

K191361

SUBMITTER INFORMATION:

Company Name: DemeTECH Corporation

Company Address: 14175 NW 60th Avenue, Miami Lakes, FL 33014

Contact Person: Tracy Chadwrick
Phone: 305-824-1048 Ext 131
Tracy.Chadwrick@demetech.us

Device Trade Name: DemeDIOX Barbed Absorbable Surgical Suture

Device Common Name: POLYDIOXANONE monofilament synthetic absorbable sutures

Class: Class II

Classification: 21 CFR 878.4840
Absorbable Barbed Polydioxanone Surgical Suture

Product Code: NEW

Predicate Devices:

The predicate is Ethicon PDS Barbed Suture, 510(k) - K113004 (The primary predicate), and the original DemeTECH Polydioxanone Synthetic Monofilament (PDO) Absorbable Suture, 510(k) - K082097 (Additional predicate).

Device Description:

DemeDIOX Barbed Absorbable Surgical Suture is an absorbable, sterile surgical monofilament suture composed of polyester, poly (p-dioxanone). The DemeTECH Suture meets all requirements in the latest edition of the USP monograph for absorbable surgical sutures with the exception of diameter. DemeDIOX Barbed Suture consists of an absorbable monofilament strand thread with spiral unidirectional barbs and is available with or without needles in a suture size 5-0 to 2. The material is dyed with D&C Violet No.2. and contains no additives. The barbing allows for tissue approximation without the use of surgical knots.

Intended Use:

DemeDIOX Barbed polydioxanone suture is indicated for use in soft tissue approximation where use of absorbable sutures is appropriate.

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 resorption to further demonstrate substantial equivalence to the predicate devices. Physical properties and functionality testing assured that the device conformed with suture diameter and suture length, extractable color and sterility to methods outlined in USP 42.

Substantial Equivalence:

Comparison Items	**DemeTECH DemeDIOX Barbed Absorbable Suture**	**DemeTECH DemeDIOX Absorbable Suture <Additional Predicate>**	**Ethicon PDS Barbed Suture (Primary Predicate>**
FDA ID#	K191361	K082097	K113004
Product Code	NEW	Same	Same
Common Name	Polydioxanone Barbed Absorbable Suture	Same	Same
Suture Characteristic	Barbed Absorbable Polydioxanone surgical suture	Absorbable Polydioxanone surgical suture	Same
Labeling	Sterile, Single Use	Same	Same
Intended Use	Soft tissue approximation	Same	Same
Technical Characteristics	Monofilament, synthetic spiral unidirectional Barbed absorbable suture is prepared from polyester, poly-(p-dioxanone)	Monofilament, synthetic non-Barbed absorbable suture is prepared from polyester, poly-(p-dioxanone)	Same
Material	Prepared from polyester, poly-(p-dioxanone)	Same	Same
Sizes	5-0, 4-0, 3-0, 2-0, 1-0, 0, 1,2	7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 1-0, 0, 1, 2	3-0, 2-0, 1-0, 0, 1
Sterilization	Ethylene Oxide (EO)	Same	Same
USP Requirements	Suture Material meets or exceeds requirements for "Absorbable Surgical Suture" in USP 42 except diameter.	Suture Material meets or exceeds requirements for "Absorbable Surgical Suture" in USP 42	Suture Material meets or exceeds requirements for "Absorbable Surgical Suture" in USP 42 except diameter

Comparison Items	DemeTECH DemeDIOX Barbed Absorbable Suture	DemeTECH DemeDIOX Absorbable Suture <Additional Predicate>	Ethicon PDS Barbed Suture (Primary Predicate>
Tensile Strength Requirements	Suture Material meets or exceeds the performance requirements defined in the USP 42 for "Tensile Strength" <881>	Same	Same
Needle Attachment Requirements	Suture Material meets or exceeds the performance requirements defined in the USP 42 for "Needle Attachment" <871>	Same	Same
Suture Length Requirements	Suture Material meets or exceeds the performance requirements defined in USP for "Suture Length Requirement" (95% of	Same	Same
Suture Packaging	Suture Material is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR	Same	Same

Clinical Tests Performed:

No clinical trials were conducted

Conclusion:

DemeDIOX Barbed Absorbable Surgical Suture is composed of the same material as the predicated devices DemeTECH DemeDIOX Polydioxanone Absorbable Suture and the Ethicon PDS Barbed Suture. It also has the same design being a sterile, flexible, monofilament absorbable thread meeting all the requirements of the United States Pharmacopeia with the exception diameter due to the small barbs created on the suture. DemeTECH's material used was selected based on known biocompatibility (per ISO 10993) and established history of use in the surgical suture industry.

The biocompatibility data and the results of performance testing presented, demonstrate the substantial equivalence of DemeTECH DemeDIOX Barbed Absorbable 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).