August 27, 2018

Demetech Corporation
% Ms. Linda Hernandez
Head of Quality
14175 NW 60th Ave
Miami Lakes, Florida 33014

Re: K181582
Trade/Device Name: DemeTECH DemeDIOX absorbable surgical suture
Regulation Number: 21 CFR 878.4840
Regulation Name: Absorbable Polydioxanone Surgical Suture
Regulatory Class: Class II
Product Code: NEW
Dated: June 12, 2018
Received: June 15, 2018

Dear Ms. Hernandez:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181582

Device Name
DemeDIOX Absorbable Surgical Suture

Indications for Use *(Describe)*
DemeDIOX Absorbable Surgical Suture is indicated for use in general soft tissue approximation including pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery, but not for use in adult cardiovascular, microsurgery and neural tissue. These sutures are useful where absorbable suture with extended wound support (up to six weeks) is desirable.

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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006 - 510(K) 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:

Luis Arguello
Phone: 305-824-1048 Ext 113
luis@demetech.us

C. Date Summary Prepared:

June 12, 2018

Trade Name:	DemeDIOX Absorbable Surgical Suture
Common Name:	POLYDIOXANONE monofilament synthetic absorbable sutures Suture
Classification Name:	Absorbable expanded Polydioxanone surgical suture
Product Code:	NEW 21 CFR 878.4840 Class II

D. Predicate Device:

The predicate is the original DEMETECH POLYDIOXANONE SYNTHETIC MONOFILAMENT (PDO) ABSORBABLE SUTURE, 510K K082097.

E. Device Description:

DemeDIOX 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 and the modification from the existence 510k K082097 is that thread is winded around the needle, a foam needle park is applied to the needle to securely hold the needle in place with the thread. One to four needles will be placed in a suture size 6-0, 5cm length, no thread attached to the needle. The material is dyed violet or un-dyed and contains no additives.

F. Intended Use:

DemeDIOX Absorbable Surgical Suture is indicated for use in general soft tissue approximation including pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery, but not for use in adult cardiovascular, microsurgery and neural tissue. These sutures are useful where absorbable suture with extended wound support (up to six weeks) is desirable.

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 and suture length, extractable color and sterility to methods outlined in USP 41.

Comparison Items	**DemeDIOX Demetech Absorbable Suture**	**Demetech Polydioxanone Absorbable Suture**
Product Code	NEW	Same
Common Name	Polydioxanone Absorbable Suture	Same
Suture Characteristic	Absorbable Polydioxanone surgical suture	Same
Labeling	Sterile, Single Use	Same
Intended Use	Soft tissue approximation	Same
Technical Characteristics	Monofilament, synthetic absorbable suture is prepared from polyester, poly-(p-dioxanone)	Same
Material	Prepared from polyester, poly-(p-dioxanone)	Same
Sizes	6-0	2-0, 3-0, 4-0, 5-0, 6-0
Sterilization	Ethylene Oxide (EO)	Same
USP Performance Requirements	Suture Material meets or exceeds performance requirements for "Absorbable Surgical Suture" in USP 40.	Same

Comparison Items	DemeDIOX Demetech Absorbable Suture	Demetech Polydioxanone Absorbable Suture
Tensile Strength Requirements	Length of the thread is too short to perform the knot pull	Suture Material meets or exceeds the performance requirements defined in the USP 40 for "Tensile Strength"<881>
Needle Attachment Requirements	Thread is not attached to the needle	Suture Material meets or exceeds the performance requirements defined in the USP 40 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)	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 and USP 40.	Same

H. Clinical Tests Performed:

No clinical trials were conducted

I. Conclusion:

DemeDIOX Absorbable Surgical Suture is composed of the same material as the predicated device **Demetech Polydioxanone Absorbable Suture** and has the same design being a sterile, flexible, monofilament absorbable thread meeting all the requirements of the United States Pharmacopeia with the exception of the needle attachment and knot pull. 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 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).

Based on the 510(k) summaries and the information provided herein we conclude that DemeTECH DemeDIOX Absorbable Surgical Suture is substantially equivalent and are safe and effective for its intended purpose.