



510(K) Summary
Polydioxanone Synthetic Absorbable Monofilament Suture

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.

Applicant:

Demetech Corporation,

8935 NW 27th Street, Miami FL. 33172

Contact Person:

A. J. Dimercurio
tony@demetech.us

Date Revised:

September 27, 2009

Device Names:

Trade Name:

DemeTECH Polydioxanone Synthetic Monofilament
(PDO) Absorbable Suture

Common Name:

DemeTECH Synthetic PDO Monofilament Absorbable
Suture

Classification Name:

Absorbable Polydioxanone Surgical Suture

Predicate Devices:

Demetech Polydioxanone (PDO) Synthetic Absorbable Suture is substantially equivalent to these predicate devices:

- CP Medical Mono-Dox Synthetic Polydioxanone Absorbable Suture
510K Number K013274, CP Medical Portland Oregon
- Ethicon PDS II Synthetic Absorbable Monofilament Suture Polydioxanone Suture
PMA Number N 18331, Ethicon Inc

Device Description:

Demetech's Polydioxanone is a synthetic monofilament absorbable surgical suture composed of polyester polymers poly (p-dioxanone) and is supplied un-dyed and dyed violet with D & C violet #2. Demetech's Polydioxanone surgical sutures meet the requirements established by the United States Pharmacopeia (U.S.P.) for synthetic absorbable surgical sutures.

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A. Intended Use:

Demetech Absorbable Polydioxanone 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.

Technological Comparison to Predicate Devices:

COMPARISON TABLE DEMETECH POLYDIOXANONE TO PREDICATE DEVICES

Suture Material is a synthetic monofilament absorbable surgical suture composed of polyester polymers poly (p-dioxanone)	Same	Same	Same
Suture material is offered un-dyed and dyed with the FDA listed colorant, D&C Violet No. 2 (21 CFR 74.3602)	Same	Same	Same
Suture Material is supplied un-coated	Same	Same	Same
Suture Material is designed being a sterile, flexible, monofilament thread offered in a variety of lengths and a range of diameters with or without various needles attached.	Same	Same	Same
Suture material absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that Polydioxanone retains approximately 85% of its original tensile strength at 120 days post implantation, with approximately 25% remaining at 180 days. Absorption polydioxanone surgical suture is essentially complete at 220 days.	Same	Same	Same to Similar
The Suture Material is " <u>Intended for Use</u> " 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.	Same	Same	Same
Suture Material meets or exceeds the performance requirements for "Absorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia 31.	Same	Same	Same



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Technological Comparison to Predicate Devices (continued)

COMPARISON TABLE TO PREDICATE DEVICES			
<u>Comparison Items</u>	Demetech Polydioxanone Suture	CP Medical Mono-Dox	Ethicon PDS II
Suture Materials meet the performance requirements for Diameter as defined in the United States Pharmacopeia 31	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 31 for " <u>Tensile Strength</u> " < 881 >	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 31 and the current edition USP 31 for " <u>Needle Attachment</u> " < 871 >	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia 31 for " <u>Suture Length Requirement</u> " (95% of stated label length)	Same	Same	Same
Suture Material is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and USP XXXI.	Same	Same	Same

Demetech Polydioxanone Suture is composed of the same material, as are the predicated devices and having the same design being a sterile, flexible, monofilament threads meeting all the requirements of the United States Pharmacopeia. Demetech Polydioxanone Synthetic Monofilament Absorbable Suture is manufactured in the same manner as the predicate devices, being composed of polyester polymers poly (p-dioxanone) and produced in operations considered standard in the fiber industry to form the finished suture fiber. The manufacturer supplies to Demetech the same suture materials as it does to other suture manufacturers including some of those listed above.

The information and the results of the performance testing presented demonstrate the substantial equivalence of Demetech's Polydioxanone Synthetic Monofilament Absorbable Suture to that of the predicate devices. It further demonstrates Demetech suture is safe and effective for its intended purpose.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JAN - 8 2010

DemeTECH Corporation
% Mr. Anthony Dimercurio
Vice President of Manufacturing
8935 NW 27th Street
Miami, Florida 33172

Re: K082097

Trade/Device Name: DemeTECH Polydioxanone Synthetic Monofilament
(PDO) Absorbable Suture

Regulation Number: 21 CFR 878.4840

Regulation Name: Absorbable polydioxanone surgical suture

Regulatory Class: Class II

Product Code: NEW

Dated: December 21, 2009

Received: January 06, 2010

Dear Mr. Dimercurio:

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.

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

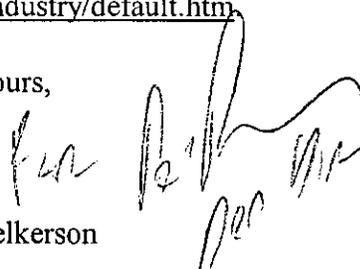
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



DemeteTECH****

Intended Use Statement

Indication for use

510K Number: _____

Device Name: Demetech Absorbable Polydioxanone Surgical Suture. As per 21CFR 878.4840

Indication for Use:

- Demetech Absorbable Polydioxanone Surgical Suture is indicated for use in all types of 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.

Prescription Use "X" And/Or Over the-Counter Use _____
(Part 21 CFR 801; Subpart D) (21 CFR 801; Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krane

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082097