DemeTECH®

JUL 17 2013

Section 1 - 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: A. J. Dimercurio
e-mail: tony@demetech.us
Phone # 305-824-1048 Ext 115

C. Date Prepared: July 15th, 2013

Trade Name: DemeCaprone (Poliglecaprone 25) Synthetic Monofilament (PGCL) Absorbable Suture

Common Name: DemeTECH Synthetic PGCL Monofilament Poliglecaprone 25 Absorbable Suture

Classification Name: Absorbable poly (glycolide/l-lactide) Surgical Suture braided or monofilament

D. Device Classification

FDA Class: II
Product Classification: 878.4493, Absorbable Poly(glycolide/l-lactide) Surgical Suture
Product Code: GAM

E. Predicate Devices: DemeCAPRONE (Poliglecaprone 25) Synthetic Absorbable Surgical Suture is substantially equivalent to these predicate devices:

- Riverpoint's Mono Q PGCL Absorbable Suture reference 510K number K100461, Riverpoint Medical. Portland OR.
- Sutures India PVT.LTD Monoglyde Poliglecaprone 25 Absorbable Suture reference 510K number K081002, Sutures India Private Limited Bangalore India.

- Ethicon's Monocryl Synthetic Absorbable Poliglecaprone 25 suture, reference 510K number, K960653 & K964072, Ethicon Inc. Somerville NJ.

F. Device Description:

DemeCAPRONE (Poliglecaprone 25) is a synthetic monofilament absorbable surgical suture composed of Poly (glycolic-co-caprolactone) copolymer (PGCL) and is supplied un-dyed and dyed with D&C Violet #2 below 0.1wt%. DemeCAPRONE (Poliglecaprone 25) synthetic absorbable suture is available in sizes 6-0 through 1 (metric sizes 0.7 – 4). DemeCAPRONE (Poliglecaprone 25) Surgical Suture meets the requirements established by the United States Pharmacopeia (U.S.P.) for synthetic absorbable surgical sutures except for diameter.

G. Intended Use:

DemeCAPRONE (Poliglecaprone 25) Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use cardiovascular surgery, microsurgery, ophthalmic surgery and neurological tissue.

H. 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-vivo 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, suture length, knot pull tensile strength, needle attachment strength, extractable color and sterility to methods outlined in USP 35.

Poliglecaprone 25 was selected based on known biocompatibility (per ISO 10993) and established history of use in the medical device industry for implantable devices, and are identical or substantially equivalent to the material used in the predicate devices listed above. Biocompatibility testing performed on Poliglecaprone 25 sutures within the submission includes the following: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Genotoxicity – Bacterial Reverse Mutation and Chromosomal Aberration, Bone Marrow Micronucleus, Subchronic Toxicity (4-week, following subcutaneous implantation), Muscle Implantation (12-week).

COMPARISON TABLE DEMETECH POLIGLECAPRONE 25 TO PREDICATE DEVICES

Comparison Items	**Demetech Poliglecaprone 25 Suture**	**Riverpoint's Mono Q PGCL Suture**	**Sutures India Monoglyde Suture**	**Ethicon Monocryl Suture**
DemeCAPRONE (Poliglecaprone 25) suture is a synthetic absorbable surgical suture. It is a sterile flexible monofilament thread, composed of Poly (glycolic-co-caprolactone) copolymer	Same	Same	Same	Same

The sutures are inert, noncollageneous and nonantigenic.	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) suture is dyed with D&C Violet #2 with content below 0.1wt%, being monofilament it is coated	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) suture is indicated for use in soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery, microsurgery or ophthalmic	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) is offered in a variety of lengths and a range of diameters with or without various needles attached.	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) suture is supplied for single use only	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) suture is sterilized by E.O. gas method	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) suture is packaged in the same or equivalent manner, and has the same or equivalent labeling claims as that of the predicate devices including indications, warnings, cautions and precautions	Same	Same	Same	Same
DemeCAPRONE meets or exceeds the performance requirements for "Absorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia except for diameter.	Same	Same	Same	Same
DemeCAPRONE meet the performance requirements for Diameter as defined in the European Pharmacopeia as dictated by the vendor of the bulk material.	Same	Same	Same	Same

DemeCAPRONE meets or exceeds the performance requirements defined in the United States Pharmacopeia for "Tensile Strength" < 881 >	Same	Same	Same	Same
DemeCAPRONE meets or exceeds the performance requirements defined in the United States Pharmacopeia and the current edition USP for "Needle Attachment" < 871 >	Same	Same	Same	Same
DemeCAPRONE meets or exceeds the performance requirements defined in the United States Pharmacopeia for "Suture Length Requirement" (95% of stated label length)	Same	Same	Same	Same
DemeCAPRONE meets the performance requirements defined in the United States Pharmacopeia current edition U.S.P. for sterility	Same	Same	Same	Same
DemeCAPRONE is packaged in a same or equivalent manner with sterile single or double packaging having labeling conforming to 21 CFR and Current edition of USP.	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) suture is biologically compatible when tested as per ISO-10993	Same	Same	Same	Same
DemeCAPRONE (Poliglecaprone 25) suture is tested and proved to be non toxic, when tested as per ISO-10993 for toxicity	Same	Same	Same	Same

I. Clinical Tests Performed:

No clinical trials were conducted

J. Conclusion:

DemeCAPRONE (Poliglecaprone 25) is composed of the same material, as are the predicated devices and the same design being a sterile, flexible, monofilament threads meeting all the requirements of the United States Pharmacopeia. DemeCAPRONE (Poliglecaprone 25) Suture is manufactured in the same manner as the predicate devices, being composed of composition of absorbable flexible, monofilament thread prepared from Poly (glycolic-co-caprolactone) copolymer (PGCL) 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 biocompatibility data and the results of performance testing presented demonstrate the substantial equivalence of DemeCAPRONE (Poliglecaprone 25) Synthetic Absorbable Suture to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 17, 2013

DemeTECH Corporation
% Anthony J. Dimercurio
Vice President RA/QA
14175 NW 60th Avenue
Miami Lakes, Florida 33014

Re: K130083
Trade/Device Name: DemeCaprone (Poligecaprone 25) Synthentic (PGCL) Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable poly(glycolide/L-lactide) surgical suture
Regulatory Class: Class II
Product Code: GAM
Dated: May 29, 2013
Received: May 31, 2013

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. 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.

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" (21CFR 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,

For Peter D. Rumm -S

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

Enclosure

DemeTECH

Section 6 - Indications for Use Statement

Indication for use

510K Number: K130083 (assigned by FDA Reviewer)

Device Name: Demetech Absorbable Poliglecaprone 25 Surgical Suture.

Indication for Use:

Demetech Absorbable Poliglecaprone 25 Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use cardiovascular surgery, microsurgery, ophthalmic surgery and neurological tissue.

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 Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130083