DemeTECH.

K123940

MAY 30 2014

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:	Luis Arguello Email: luis@demetech.us Phone # 305-824-1048 Ext 113
	Alternate Contact	Anthony J Dimercurio, tony@demetech.us
C.	Date Prepared:	May 29, 2014
D.	Trade Name:	DemeQUICK (Rapid Absorbable) Surgical Suture
	Common Name:	PGLA Rapid Absorbable Surgical Suture
	Classification Name:	Absorbable poly (glycolide/l-lactide) Surgical Suture braided or monofilament

E. Predicate Devices: DemeQUICK (Rapid Absorbable) Surgical Suture is substantially equivalent to these following two predicate devices:

- Riverpoint's Vilet Quick® Synthetic Absorbable suture, reference 510k number, K120556, Portland, OR.
- Ethicon's Vicryl Rapide® Synthetic Absorbable suture, reference 510K number, K033746, Ethicon Inc. Somerville NJ.

F. Device Description:

DemeQUICK Absorbable suture is an absorbable sterile surgical suture composed of copolymers made from 90% glycolide and 10% L-lactide. DemeQUICK Absorbable suture is coated with a copolymer made from 30% glycolide 70% L-lactide and calcium stearate, it is available un-dyed from sizes: USP 6-0 to USP 2. The DemeQUICK Absorbable suture complies with the requirements established by the United States Pharmacopoeia (USP) for absorbable suture, with tensile strength meeting the collagen table.

G. Intended Use:

DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture is indicated for use in general soft tissue approximation (i.e., mucosa and skin) where only short term wound support (7-10 days) is required. DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture is not intended for use in ligation, cardiovascular, ophthalmic or neurological procedures.

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-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 35.

COMPARISON TABLE DEMEQUICK ABSORBABLE TO PREDICATE DEVICES

Comparison Items	**DemeQUICK Absorbable Suture**	**Riverpoint Medical Vilet Quick® Suture**	**Ethicon Vicryl Rapide® Suture**
Suture meets or exceeds the performance requirements for "Absorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia.	Same	Same	Same
Suture Materials meet the performance requirements for Diameter as defined in the United States and European Pharmacopeias	Same	Same	Same
Suture meets or exceeds the performance requirements defined in the United States Pharmacopeia for "Tensile Strength" < 881 > collagen	Same	Same	Same
Suture Material meets or exceeds the performance requirements defined in the United States Pharmacopeia and the current edition USP for "Needle Attachment" < 871 >	Same	Same	Same
Suture meets or exceeds the performance requirements defined in the United States Pharmacopeia for "Suture Length Requirement" (95% of stated label length)	Same	Same	Same
Suture is packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and current edition of USP.	Same	Same	Same
Suture Material is a composition of absorbable flexible, braided thread prepared from 90% glycolide and 10% L-lactide	Same	Same	Same

Suture material is offered un-dyed	Same	Same	Same
Suture material is supplied coated	Same	Same	Same
Suture is sterilized by Gamma Irradiation	Same	Same	Same
Suture Material is designed being a sterile, flexible, braided thread offered in a variety of lengths and a range of diameters with or without various needles attached.	Same	Same	Same
Progressive loss of tensile strength and eventual absorption of DemeQUICK (Rapid Absorbable) Surgical Suture occurs by means of hydrolysis. Absorption begins as a loss of tensile strength followed by a loss of mass. Absorption is essentially complete in approximately 30 to 40 days.	Same	Same	Same
DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture is indicated for use in general soft tissue approximation (i.e., mucosa and skin) where only short term wound support (7-10 days) is required. DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture is not intended for use in ligation, cardiovascular, ophthalmic or neurological procedures.	Same	Same	Same

DemeQUICK (Rapid Absorbable) Surgical Suture is composed of the same material as are the predicated devices using the same design' being a sterile, flexible, multifilament threads meeting the requirements of the United States Pharmacopeia. DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture is manufactured in the same manner as the predicate devices, being produced from 90% glycolide and 10% L-lactide manufactured in operations considered standard in the fiber industry to form the finished suture fiber in bulk. The manufacturer supplies the identical bulk fibers to Demetech as it sells to other suture manufacturers including those with approved 510K submissions.

A summary of recent USP performance testing results are presented below on gamma sterilized finish sutures, together with the gamma sterilized Biocompatibility documentation already submitted to FDA, demonstrates the substantial equivalence of DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture to that of the predicated 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 20993-0002

May 30, 2014

DemeTECH Corporation
% Mr. John O'Brien
AJW Technology Consultants Incorporated
445 Apollo Beach Boulevard
Apollo Beach, Florida 33572

Re: K123940
Trade/Device Name: DemeQUICK (Rapid Absorbable) Surgical 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 7, 2014
Received: May 28, 2014

Dear Mr. O'Brien:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

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

DemeTECH.

Section 2 - Indications for Use Statement

Indication for use

510K Number: K123940 (assigned by FDA Reviewer)

Device Name: DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture

Indication for Use:

DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture is indicated for use in superficial soft tissue approximation (i.e., mucosa and skin) where only short term wound support (7-10 days) is required. DemeQUICK (Rapid Absorbable) Synthetic Surgical Suture is not intended for use in ligation, cardiovascular, ophthalmic or neurological procedures.

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)

Peter L. Hudson -S
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