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).

<table>
<thead>
<tr>
<th>COMPARISON TABLE DEMETECH POLIGLECAPRONE 25 TO PREDICATE DEVICES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comparison Items</strong></td>
</tr>
<tr>
<td>DemeCAPRONE (Poliglecaprone 25) suture is a synthetic absorbable surgical suture. It is a sterile flexible monofilament thread, composed of Poly (glycolic-co-caprolactone) copolymer</td>
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<tr>
<td>The sutures are inert, noncollagenous and nonantigenic.</td>
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<td>-----------------------------------------------------</td>
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<tr>
<td>DemecAPRONE (Poliglecaprone 25) suture is dyed with D&amp;C Violet #2 with content below 0.1wt%, being monofilament it is coated</td>
</tr>
<tr>
<td>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</td>
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<tr>
<td>DemecAPRONE (Poliglecaprone 25) is offered in a variety of lengths and a range of diameters with or without various needles attached.</td>
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<tr>
<td>DemecAPRONE (Poliglecaprone 25) suture is supplied for single use only</td>
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<tr>
<td>DemecAPRONE (Poliglecaprone 25) suture is sterilized by E.O. gas method</td>
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<tr>
<td>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</td>
</tr>
<tr>
<td>DemecAPRONE meets or exceeds the performance requirements for &quot;Absorbable Surgical Suture&quot; as defined in the Official Monograph of the United States Pharmacopeia except for diameter.</td>
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<tr>
<td>DemecAPRONE meet the performance requirements for Diameter as defined in the European Pharmacopeia as dictated by the vendor of the bulk material.</td>
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<tr>
<td>Requirement</td>
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<tr>
<td>----------------------------------------------------------------------------</td>
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<tr>
<td>DemeCAPRONE meets or exceeds the performance requirements defined in the United States Pharmacopeia for “Tensile Strength” &lt; 881 &gt;</td>
</tr>
<tr>
<td>DemeCAPRONE meets or exceeds the performance requirements defined in the United States Pharmacopeia and the current edition USP for “Needle Attachment” &lt; 871 &gt;</td>
</tr>
<tr>
<td>DemeCAPRONE meets or exceeds the performance requirements defined in the United States Pharmacopeia for “Suture Length Requirement” (95% of stated label length)</td>
</tr>
<tr>
<td>DemeCAPRONE meets the performance requirements defined in the United States Pharmacopeia current edition U.S.P. for sterility</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>DemeCAPRONE (Poliglecaprone 25) suture is biologically compatible when tested as per ISO-10993</td>
</tr>
<tr>
<td>DemeCAPRONE (Poliglecaprone 25) suture is tested and proved to be non toxic, when tested as per ISO-10993 for toxicity</td>
</tr>
</tbody>
</table>

**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.
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” (21 CFR Part
807.97). For questions regarding the reporting of adverse events under the MDR regulation (21

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

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
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 in 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