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

Re: K181578
Trade/Device Name: DemeTECH PTFE Nonabsorbable Surgical Suture
Regulation Number: 21 CFR 878.5035
Regulation Name: Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: NBY
Dated: April 6, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Peter L. Hudson -S
2018.10.11 09:33:52 -04'00'

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
510(k) Number (if known)
K181578

Device Name
DemeTECH PTFE Suture

Indications for Use (Describe)
The DemeTECH PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general surgeries. The device is not indicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.
Section 5 - 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: April 6, 2018

Trade Name: xxx
Common Name: PTFE Nonabsorbable Surgical Suture
Classification Name: Non-absorbable expanded polytetrafluoroethylene surgical suture
Product Code: NBY 21 CFR 878.5035 Class II

D. Predicate Devices: The DemeTECH PTFE Suture is substantially equivalent to the predicates Cytoplast PTFE suture and Look PTFE Suture in which the basic features and intended uses are the same. Any differences between the DemeTECH PTFE Suture and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

- Osteogenics Biomedical, Inc. Cytoplast PTFE Suture reference 510k number K072076
- Surgical Specialties Corporation LOOK PTFE Suture reference 510k number K160744

E. Device Description:

DemeTECH PTFE Suture is a nonabsorbable, sterile surgical monofilament suture composed of polytetrafluoroethylene. The DemeTECH PTFE Suture meets or exceeds all requirements in the latest edition of the USP monograph for nonabsorbable surgical sutures and is provided sterile in various sizes and configurations. The material is undyed and contains no additives and is white in appearance and may be provided with or without an attached needle(s).

F. Intended Use:
The DemeTECH PTFE Suture is indicated for use in all types of soft tissue approximation and/or ligation, including dental and general surgeries. The device is not indicated for use in ophthalmic surgery, microsurgery, and peripheral neural tissue.

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, suture length, knot pull tensile strength, needle attachment strength, extractable color and sterility to methods outlined in USP 39.

### COMPARISON TABLE

<table>
<thead>
<tr>
<th>Comparison Items</th>
<th>Demetech PTFE Nonabsorbable Suture</th>
<th>Look PTFE Nonabsorbable Suture</th>
<th>Cytoplast PTFE Nonabsorbable Suture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code</td>
<td>NBY</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Common Name</td>
<td>PTFE nonabsorbable suture</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Suture Characteristic</td>
<td>Nonabsorbable polytetrafluoroethylene surgical suture</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Labeling</td>
<td>Sterile, Single Use</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Intended Use</td>
<td>Approximation or ligation of soft tissues</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Technical Characteristics</td>
<td>Monofilament, uncoated, synthetic nonabsorbable suture</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Material</td>
<td>High-density polytetrafluoroethylene (PTFE)</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Sizes</td>
<td>2-0</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Ethylene Oxide (EO)</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>USP Performance Requirements</td>
<td>Suture Material meets or exceeds performance requirements for “Nonabsorbable Surgical Suture” in USP 39.</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Tensile Strength Requirements</td>
<td>Suture Material meets or exceeds the performance requirements defined in USP for “Tensile Strength” &lt; 881 &gt;</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Needle Attachment Requirements</td>
<td>Suture Material meets or exceeds the performance requirements defined in USP for “Needle Attachment” &lt; 871 &gt;</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Suture Length Requirements</td>
<td>Suture Material meets or exceeds the performance requirements defined in USP for “Suture Length Requirement” (95% of stated label length)</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Suture Packaging</td>
<td>Device wound onto inner support card, within a Tyvek / Poly pouch</td>
<td>Device wound onto inner support card, within a Tyvek/Poly Primary Pouch; inside a Tyvek / Poly secondary pouch</td>
<td>Device wound onto inner support card, within a Tyvek / Poly pouch</td>
</tr>
</tbody>
</table>

H. **Clinical Tests Performed:**

No clinical trials were conducted

I. **Conclusion:**

DemeTECH PTFE Nonabsorbable Surgical Suture is composed of the same material as the predicate devices and has the same design being a sterile, flexible, monofilament nonabsorbable thread meeting all the requirements of the United States Pharmacopeia. 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 PTFE Nonabsorbable 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 PTFE Nonabsorbable Surgical Suture is substantially equivalent for its intended purpose.