JUN 1 8 2003

DEMETECH CORP **510(k) Summary of Safety and Effectiveness**

for 510 (k) No. K023028

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

(A)(1) *Submitter's name*: DemeTECH Corp
Submitter's address: 12119 SW 131 Ave.
Miami, FL 33186

Submitter's telephone number: (305) 251-2700

Contact Person: Mr. Luis Arguello, President

Date Summary Prepared: September 7, 2002

(2) *Trade or proprietary device name*: DemeTECH Nylon Nonabsorbable Suture

Common or usual name: Nylon Nonabsorbable Surgical Suture

Classification Name: Nonabsorbable Polyamide Surgical Suture
Panel: General and Plastic Surgery
Class: II

(3) *Legally marketed predicate device*: Grams Nylon Nonabsorbable Suture [Grams American Suture, Inc., Grafton, WI] (510(k) No.: K003000)

(4) *Subject device description*:

The DemeTECH Nylon Nonabsorbable Suture is a single use, individually packaged, disposable nonabsorbable nylon (polyamide) surgical suture.

(5) *Subject device intended use*:

The DemeTECH Nylon Nonabsorbable Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic and neurological procedures.

(6) *Performance data*:

The DemeTECH Nylon Nonabsorbable Suture has been demonstrated as both equivalent to the predicate device and meets United States Pharmacopeia (USP) 23 and 24 requirements for Nonabsorbable Surgical Sutures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2003

Mr. Luis Arguello
President
DemeTECH Corporation
12119 SW 131 Avenue
Miami, Florida 33186

Re: K023028
Trade/Device Name: DemeTECH Nylon Nonabsorbable Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable polyamide surgical suture
Regulatory Class: II
Product Code: GAR
Dated: April 25, 2003
Received: May 8, 2003

Dear Mr. Arguello:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. Indications for use of the Device

510(k) Number): Not known K023028

Device Name: DemeTECH Nylon Nonabsorbable Suture

Indications for Use:

The DemeTECH Nylon Nonabsorbable Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular and ophthalmic and neurological procedures.

(Please do not write below this line—continue on another page if needed)

* * * * * * * * * *

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023028

Prescription Use X or **Over-the-Counter Use** _____
(Per 21 CFR 801.109)