K043539 pg. 1 of 1

APR 6 2005

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

DemeTECH
3530 NW 115th Ave.
Miami, FL 33178
U.S.A

Phone: 305-597-5277
Fax: 305-437-7607

Contact Person: Luis Arguello

Date of Summary: January 1, 2005

Trade/Proprietary Name: DemeTECH Sterile Synthetic Absorbable Sutures (PGA) and Needles

Classification Name: Suture, Absorbable, Synthetic, Polyglycolic Acid

Product Code: GAM

Predicate Device: K984374 Surgisorb - Samyang Corp.

Intended Use:

The PGA Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not for use in cardiovascular or neurological tissue.

Device Description:

Description: Polyglycolic Acid (PGA) is a sterile absorbable synthetic, multifilament suture composed of glycolic acid. The yarns are braided and coated with a blend of polycaprolate, copolymer of caprolactone and glycolide. The PGA Suture is available in violet from sizes: USP8/0 USP2.

PGA fulfills all the requirements of USP and the European Pharmacopoeia for sterile, synthetic, absorbable sutures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2005

Demetech Corporation
c/o Mr. Arthur J. Ward
AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K043539
Trade/Device Name: DemeTECH Sterile Synthetic Absorbable Sutures (PGA) and Needles
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(glycolide/L-lactide) Surgical Suture
Regulatory Class: II
Product Code: GAM
Dated: March 8, 2005
Received: March 17, 2005

Dear Mr. Ward:

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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

K043539

Indications for Use

510(k) Number (if known): K043539

Device Name: DemeTECH Sterile Synthetic Absorbable Sutures (PGA) and Needles

Indications for Use:

The PGA Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not for use in cardiovascular or neurological tissue.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...orative

...es

K043539