MAY 16 2005

K043330 pg 1 of 2

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: November 1, 2004

Trade/Proprietary Name: DemeTECH Polypropylene Surgical Sutures

Classification Name: Suture, nonabsorbable, synthetic, polypropylene

Product Code: GAW

Predicate Device: Pronova Non-Absorbable Suture - Ethicon K001625

Intended Use:

The DemeTECH Polypropylene Surgical Suture is indicated for use in general soft tissue approximation and/or litigation including use in cardiovascular, ophthalmic, and neurological procedures.

Device Description:

The DemeTECH polypropylene sutures are inert, non-absorbable, sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polylefin. The suture is pigmented to enhance visibility.

Size Range	10-0 to 8-0 and 6-0 to 2	10-0 to 8-0 and 6-0 to 2
Thread Diameter		
U.S.P sizes	10-0 to 8-0 and 6-0 to 2	10-0 to 8-0 and 6-0 to 2
Metric sizes in mm	0.2 to 0.4 and 0.7 to 5.0	0 - .350 to .399mm
Packaging	Cartons of 12, 24 and 36	Cartons of 12, 24 and 36
Thread Length	45 -100 cm	Variety of Lengths
Thread Color	Pigmented Blue	Pigmented and Clear
Sterilization	Ethylene Oxide	Ethylene Oxide
Application	Single Use Only	Single Use Only

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

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

Re: K043330
Trade/Device Name: Deme*Tech* Polypropylene Surgical Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: II
Product Code: GAW
Dated: April 27, 2005
Received: April 28, 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,

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

K043330

Indications for Use

510(k) Number (if known): K043330

Device Name: *DemeTECH* Polypropylene Surgical Suture

Indications for Use:

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

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)

K043330