APR 30 2008

K072930
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DemeTECH®

Summary of Safety & Effectiveness
Absorbable Surgical Gut Suture (Plain and Chromic)

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
3530 NW 115 Ave
Miami FL. 33178

B. Contact Person:
Anthony J. Dimercurio

Phone 262-387-1610

C. Date Prepared:

October 8, 2007

D. Device Name:

- **Trade Name:** Demetech Absorbable Surgical Gut Suture Plain & Chromic
- **Common Name:** Plain & Chromic Cat Gut Absorbable Suture
- **Classification Name:** Absorbable Surgical Gut Suture

E. Predicate Devices: Demetech Absorbable Surgical Gut Suture is substantially equivalent to these predicate devices:

- AESCULAP Absorbable Surgical Gut Suture, Plain & Chromic & Softcat Gut Suture, 510K Number K991223, AESCULAP, San Diego California.
- T. Cad International, Plain/Chromic Catgut Suture, Trading Consultants& Distributors International Inc. 510K Number K994002, Chicago IL.
- CP Medical, Plain and Chromic Absorbable Surgical Gut Suture, 510K Number K001299, CP Medical Portland Oregon.

F. Device Description:

Demetech Surgical gut suture (Plain and Chromic) is an absorbable sterile surgical suture composed of purified connective tissue (mostly collagen) derived from either the serosal layer of beef (bovine) or the submucosal fibrous layer of sheep (ovine) intestines.

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G. Intended Use:

"Demetech Absorbable Surgical Gut Suture (Plain and Chromic) is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures".

H. Technological Comparison to Predicate Devices:

COMPARISON TABLE DEMETECH TO PREDICATE DEVICES

Comparison Items	Demetech	T. Cad International	CP Medical	AESCULAP
Absorbable Surgical Gut Suture (Plain & Chromic) is an absorbable, sterile, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine.	Same	Same	Same	Same
Absorbable Surgical Gut Suture (Plain & Chromic) is "Intended for Use" in soft tissue approximation and /or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.	Same	Same	Same	Same
Absorbable Surgical Gut Suture (Plain & Chromic) supplied for single use only, with or without needles attached, uncoated or coated with a glycerol solution.	Same	Same	Similar	Same
Absorbable Surgical Gut Suture (Plain & Chromic) is packed with a packet fill solution of 90% Isopropyl Alcohol, 0.5% Diethanolamine 0.5% Sodium Benzoate and water q.s ad 100%	Same	Similar	Similar	Similar
Absorbable Surgical Gut Suture (Plain & Chromic) packaged in the same or equivalent manner, and has the same or equivalent labeling claims as the predicate devices including indications, contraindications, warnings, cautions, and precautions.	Same	Same	Same	Same
Finished suture material meets or exceeds the performance requirements for "Absorbable Surgical Suture" as defined in the Official Monograph of the United States Pharmacopeia 23 and the current edition USP 24.	Same	Same	Same	Same

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Technological Comparison to Predicate Devices Continued:

Comparison Items	Demetech	T. Cad International	CP Medical	AESCULAP
Finished suture material meets the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Diameter" < 861 >	**Same**	**Same**	**Same**	**Same**
Finished suture material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Tensile Strength" < 881 >	**Same**	**Same**	**Same**	**Same**
Finish suture material meets or exceeds the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Needle Attachment" < 871 >	**Same**	**Same**	**Same**	**Same**
Finished suture material meets the performance requirements defined in the United States Pharmacopeia 23 and the current edition USP 24 for "Finish suture Length Requirement" (95% of stated label length)	**Same**	**Same**	**Same**	**Same**
Finished suture material packaged in a same or equivalent manner with sterile single or double package having labeling conforming to 21 CFR and USP XXIV.	**Same**	**Same**	**Same**	**Same**

I. Conclusion:

Demetech Absorbable Gut Suture (Plain & Chromic) is composed of the same material, as are the predicated devices and the same design, being a sterile, flexible, monofilament like threads meeting all the requirements of the United States Pharmacopeia. Demetech Absorbable Gut Suture (Plain & Chromic) is manufactured in the same manner as the predicate devices, being produced from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine, and produced in operations considered standard in the industry to form the finished suture strand. The raw suture material manufacturer supplies to Demetech Suture the same suture materials as it does to other suture manufacturers, which may include some of them listed above.

The results of the performance testing data presented demonstrate the substantial equivalence of Demetech Absorbable Gut Suture (Plain & Chromic) to that of the predicated devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DemeTECH
% Mr. Anthony J. Dimercurio
Vice President of MFG
3530 NW 115 Avenue
Miami, Florida 33178

APR 30 2008

Re: K072930
Trade/Device Name: Absorbable Surgical Gut Suture
Regulation Number: 21 CFR 878.4830
Regulation Name: Absorbable surgical gut suture
Regulatory Class: II
Product Code: GAL
Dated: February 22, 2008
Received: April 11, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072930

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Indication for use

510K Number: K072930

Device Name: Absorbable Surgical Gut Suture. As per **21CFR 878.4830**

Indication for Use:

Demetech Absorbable Surgical Gut Suture (Plain and Chromic) is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures".

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072930

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