K994002

FEB 4 2000

T.CAD International
990930/MG-510(k)
CATGUT

SECTION III

510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and Title 21 CFR §807.92

A. Applicant & Submitted By:

Trading Consultants And Distributors International Inc.
(T.CAD International)
157 WindDance Dr.
Chicago, IL 60046-6681
Telephone: (847) 265-7676
Fax. : (847) 265-7686

Contact Person: Main M. Ghazal, President
Date Prepared: October 2nd 1999.

B. Device Name:

a. Trade Name: PLAIN/CHROMIC CATGUT
b. Common or Usual Name: Absorbable Surgical Gut Sutures, Plain & Chromic
c. Classification Name: Absorbable surgical gut Suture. (Per 21CFR878.4830)

C. Predicate Device:

Plain and Chromic Absorbable Surgical Sutures of Davis & Geck (K930589)
SOFTGUT® Plain and Chromic Absorbable Surgical Suture (Davis & Geck)

D. Device Description:

CATGUT, Plain and 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, and 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. CATGUT meets the United States Pharmacopeia (U.S.P.) standards for Absorbable Surgical Sutures. It will be offered uncoated or coated with glycerol and with or without standard needles attached.

E. Intended Use:

CATGUT 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.

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F. Comparison to Predicate Device:

	CATGUT	Predicate Device
Intended Use	CATGUT 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.	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.
Suture Material	Absorbable, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine	Absorbable, flexible thread prepared from either the serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine
Suture Characteristics	Factors which can affect tensile strength loss and absorption rates are: a. Type of suture-Plain gut generally is expected to absorb more rapidly than chromic gut. b. Infection-Surgical gut is absorbed more rapidly in infected tissue than in non-infected tissue. Tissue Sites-Surgical gut will absorb more rapidly in tissue where increased levels of proteolytic enzymes are present, as in the secretions exhibited in the stomach, cervix and vagina.	Same
Sterilization Method	Gamma Irradiation	Same or equivalent method
How Supplied	Sterile and undyed. Offered for Single Use Only with or without surgical needles. Also offered uncoated or coated with glycerol.	Same or equivalent manner. SOFTGUT® is offered coated with glycerol.
Suture Diameter, Suture Length, Knot Pull Tensile Strength and Needle Attachment Strength	Meet U.S.P. Requirements	Meet U.S.P. Requirements

K994502

Packaging	Packaged with an alcohol solution in Aluminum Foil and Polyester tear open packaging.	Same or equivalent manner.
Labeling	In conformance with CDRH instructions of the "Medical Device Quality Manual" dated December 1996. Package Inserts in accordance with the FDA Guidance documents " Alternate Suture Labeling" Resulting from the January 11th 1993 meeting with HIMA, reformatted on December 17th 1997.	Same

G. Clinical & Non-Clinical Testing:

Non-Clinical Testing was conducted on the subject device to prove conformance to the requirements of U.S.P. standards and to demonstrate substantial equivalence to the predicate device. Physical properties and functionality testing assured the safety and effectiveness of the subject device within its intended uses. Results of the non-clinical testing demonstrate conformance with the U.S.P. standards and requirements for Absorbable surgical suture.

Clinical Testing: Not available at the present time.

H. Conclusion:

Based on the technological characteristics and physical properties of the device, the device description, the intended use of the device, and conformance with voluntary performance standards like:

a. United States Pharmacopeia Standards
b. ISO 9002, EN 46002 & EN 552 Standards
c. FDA Guidance documents " Alternate Suture Labeling" Resulting from the January 11th 1993 meeting with HIMA.

T.CAD International believes that the subject device demonstrates a substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 2000

Mr. Main M. Ghazal
Trading Consultants and Distributors International, Inc.
157 WindDance Drive
Chicago, Illinois 60046-6681

Re: K994002
Trade Name: Plain/Chromic Catgut
Regulatory Class: II
Product Code: GAL
Dated: November 22, 1999
Received: November 24, 1999

Dear Mr. Ghazal:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Monday, December 11, 1989 (Vol. 54, No. 236, Pages 50737 and 50738). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Plain/Chromic Catgut Surgical Suture 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.

2. This device may not be manufactured from any material other than serosal connective tissue layer of beef (bovine) or the submucosal fibrous tissue of sheep (ovine) intestine. In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacturing of the Plain/Chromic Catgut surgical suture. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed change(s).

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4595. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R. Ogden for JEO

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994002

T.CAD International
990930/MG-510(k)
CATGUT

SECTION II

Statement of indication for use

Device Name: PLAIN/CHROMIC CATGUT

510(k) Number:

Indication for use:

CATGUT 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.

MRO for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994002

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21CFR 801.109)