K991073

JUL 30 1999

510(k) Summary
CardioThoracic Systems, Inc.
Acier Sutures
510(k) Notification K991073

GENERAL INFORMATION

Manufacturer:
Peters Pharmaceutical Laboratory
42 Rue Benoit Frachon
Bobigny, France 93000

Distributed By:
CardioThoracic Systems, Inc.
10600 North Tantau Avenue
Cupertino, California 95014
Est. Registration No. 9027735

Contact Person: Michael J. Billig
Vice President, Regulatory, Quality, and Clinical Research

Date Prepared: March 25, 1999

DEVICE DESCRIPTION

Classification: Suture, Nonabsorbable, Steel, Monofilament and Multifilament Surgical Suture

Trade Name: Acier

Generic/Common Name: Surgical Sutures

PREDICATE DEVICES

Ethicon's Ethi-Pack Surgical Stainless Steel Suture; K931271

INTENDED USE

Acier Steel Suture is indicated for use in abdominal wound closure, intestinal anastomosis, hernia repair, and sternal closure.

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PRODUCT DESCRIPTION

Acier Steel Suture is a nonabsorbable sterile surgical suture composed of 316L stainless steel.

SUBSTANTIAL EQUIVALENCE

The Peters Acier sutures are substantially equivalent to the predicate devices (Ethicon's Ethi-Pack Surgical Stainless Steel Suture; K931271) in regards to intended use, design, composition, function, indications, patient population and performance. Any differences between the Peters Acier sutures and its predicate device do not raise any new issues of safety and effectiveness.

Functional bench testing has been conducted on the Acier sutures and the results of the testing verified that the sutures perform as designed, are suitable for their intended use.

SUMMARY

As contained in this 510(k) summary, the Peters Acier sutures are substantially equivalent to the predicate devices identified in that the sutures have the same intended use and are similar in design, composition, function, patient population and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Mr. Michael J. Billig
Cardio Thoracic Systems, Inc.
10600 N. Tantau Avenue
Cupertino, California 95014-0739

Re: K991073
Trade Name: Acier Stainless Steel Suture
Regulatory Class: II
Product Code: GAQ
Dated: June 25, 1999
Received: June 28, 1999

Dear Mr. Billig:

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 will be announced in a future Federal Register notice. 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 Acier Surgical Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure, and certain orthopedic procedures including cerclage and tendon repair.

2. This device may not be manufactured from any metal other than 316L stainless steel. 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 manufacture of the Acier surgical suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

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

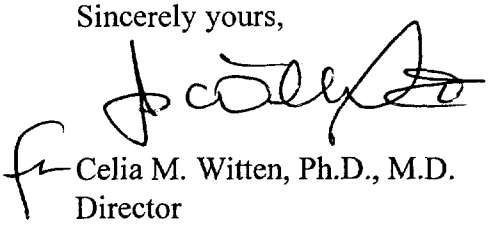
The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

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) 594-4639. 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,



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

Enclosure

K991073

510(k) Number (if known): K991073

Device Name: ACIER STAINLESS STEEL SUTURE

Indications For Use:

Surgical Suture is indicated for use in abdominal wound closure, hernia repair, sternal closure, and certain orthopedic procedures including cerclage and tendon repair.

(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 Devices
510(k) Number K991073

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)