

MAR 17 1998

K963965

CardioThoracic Systems, Inc.
510(k) Summary
Vascular Stitcher
510(k) Notification K963965

GENERAL INFORMATION

Manufacturer: CardioThoracic Systems, Inc.
10600 North Tantau Avenue
Cupertino, California
(408) 342-1700
(408) 342-1717 FAX
Est. Reg. No. (awaiting issuance)

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

Date Prepared: September 28, 1996

DEVICE DESCRIPTION

Classification: Class I

Trade Name: Vascular Stitcher

Generic/Common Name: Needle Holder/Needle Driver

PREDICATE DEVICES

- (1) Young Boomerang Needle Holder
- (2) Harris Boomerang Needle Holder
- (3) Millin Boomerang Needle Holder
- (4) U.S. Surgical EndoStitch Suturing Instrument
- (5) U.S. Surgical Endoscopic Needle Driver

INTENDED USE

The Vascular Stitcher is intended to be used in performing vascular suturing in general surgery, including endoscopic procedures.

PRODUCT DESCRIPTION

The Vascular Stitcher is a stainless steel surgical product designed for use with CTS compatible needle and suture in a semi-automatic or manually operated mode. The Vascular Stitcher is designed for use with or without trocar sleeves depending on the endoscopic technique or whether during minimally invasive surgical procedures.

SUBSTANTIAL EQUIVALENCE

The Vascular Stitcher is substantially equivalent to other predicate devices currently being marketed. The marketed predicate devices are identified above. The Vascular Stitcher is substantially equivalent to the predicate devices with regard to intended use, function, physical characteristics, and materials.

SUMMARY

As contained in this 510(k) summary, the Vascular Stitcher is substantially equivalent to the predicate devices identified, in that, the stitcher has similar functions and is composed of similar materials as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael J. Billig
Vice President, Regulatory, Quality, and Clinical Research
10600 N. Tantau Avenue
Cupertino, California 95014-0739

MAR 17 1998

Re: K963965
Trade Name: Vascular Stitcher
Regulatory Class: II
Product Code: GEI
Dated: December 22, 1997
Received: December 24, 1997

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 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). 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.

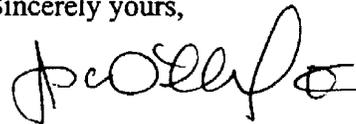
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21-CFR-Part-820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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

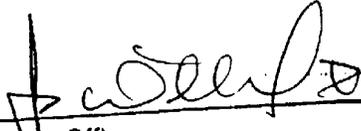
501(k) Premarket Notification
Vascular Stitcher

Vascular Stitcher
510(k) Premarket Notification

STATEMENT OF INDICATIONS OF USE

The Vascular Stitcher is intended to be used in performing vascular suturing in general surgery, including endoscopic procedures.

Prescription Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices | 1496396S
510(k) Number _____