K992833

NOV 10 1999

510(k) Summary
CardioThoracic Systems, Inc.
Vacuum Assist Stabilizer
510(k) Notification K_____

GENERAL INFORMATION

Manufacturer:
CardioThoracic Systems, Inc.
10600 North Tantau Avenue
Cupertino, California
(408) 342-1700
(408) 342-1717 FAX
Est. Reg. No. 9027735

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

Date Prepared:
August 1999

DEVICE DESCRIPTION

Classification:
Cardiovascular Surgical Instruments (21 CFR section 870.4500)

Trade Name:
CTS Vacuum Assist Stabilizer

Generic/Common Name:
Cardiovascular Surgical Instrument

PREDICATE DEVICES

Octopus2 Tissue Stabilization System manufactured by Medtronic (K964445)

INTENDED USE

The CTS Vacuum Assist Stabilizer is intended for use during the performance of minimally invasive cardiac surgery. Used in conjunction with the CTS Ultima OPCAB System, the stabilizer isolates and provides local immobilization of the target vessel on the beating heart.

PRODUCT DESCRIPTION

The CTS Vacuum Assist Stabilizer consists of a curved shaft with an articulating foot at the distal end and a mount that connects to the CTS AccessRail™ Platform. The stabilizer provides local immobilization of an anastomotic site.

SUBSTANTIAL EQUIVALENCE

The safety and effectiveness of the Vacuum Assist Stabilizer is substantially equivalent to the predicate device (Medtronic's Octopus2 Tissue Stabilization System; K964445) in regards to intended use, technology, functionality, applicable patient population and performance. Any differences between the CTS Vacuum Assist Stabilizer and its predicate device does not raise any new issues of safety and effectiveness.

Functional bench, animal and histology testing has been conducted and the results of the testing verified that the Vacuum Assist Stabilizer performs as designed and is suitable for its intended use.

SUMMARY

As contained in this 510(k) summary, the CTS Vacuum Assist Stabilizer is substantially equivalent to the predicate device identified in that the Vacuum Assist Stabilizer has a similar intended use, technology, functionality, patient population and performance as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Michael J. Billig
Vice President, Regulatory, Quality and Clinical Research
CardioThoracic Systems, Inc.
10600 North Tantau Avenue
Cupertino, CA 95014-0739

Re: K992833
Trade Name: CTS Vacuum Assist Stabilizer
Regulatory Class: I
Product Code: MWS
Dated: August 20, 1999
Received: August 23, 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 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). 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.

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) 594-4586. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon for

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardioThoracic Systems, Inc.
CTS Vacuum Assist Stabilizer
510(k) Premarket Notification

STATEMENT OF INDICATIONS FOR USE

The CTS Vacuum Assist Stabilizer is intended for use during the performance of minimally invasive cardiac surgery. Used in conjunction with the CTS Ultima™ OPCAB™ System, the stabilizer isolates and provides local immobilization of the target vessel on the beating heart.

for C. Sloan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992833