

510(k) Summary
CardioThoracic Systems, Inc.
CTS FloCoil™ Shunt
510(k) Notification K970638

GENERAL INFORMATION

OCT 30 1997

Manufacturer: CardioThoracic Systems, Inc.
10600 N. 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

DEVICE DESCRIPTION

Classification: Class II

Trade Name: CTS FloCoil™ Shunt

Generic/Common Name: Vascular clamp (21 CFR 870.4450)
Surgical Vessel Dilator (21 CFR 870.4475)
Blood Access Device and Accessories (21 CFR 876.5540)

PREDICATE DEVICES

- (1) Bio-Vascular, Inc. Flo-Rester
- (2) Research Medical, Inc. Yacoubian Clamp External Coronary Artery Occluder
- (3) Research Medical, Inc. Carotid Artery Shunts
- (4) Research Medical, Inc. Vacu-Sponge Surgical Sponge

INTENDED USE

The CTS FloCoil Shunt is designed to help reduce blood in the operative field by temporary occlusion of the artery and to provide blood flow distal to the arteriotomy. This FloCoil Shunt is not an implant and is removed prior to completion of the anastomosis.

PRODUCT DESCRIPTION

The CTS FloCoil Shunt consists of coil reinforced polymer shaft with a polymer seal on each end and tapered polymer tips. The polymer seals on each end contact the vessel wall and cause occlusion of the artery proximal and distal to the arteriotomy. The FloCoil Shunt is selected according to the outer diameter of the polymer seals and is available in various sizes for various vessel diameters. There is a hole in both tapered tip ends of the FloCoil Shunt to allow for the perfusion of blood through the shunt's inner lumen and beyond the arteriotomy. A polyester thread (tether) is attached to the FloCoil Shunt in the middle of the shaft. Attached to the tether is a radiopaque tab which is used to aid insertion and removal of the FloCoil Shunt.

SUBSTANTIAL EQUIVALENCE

The CTS FloCoil Shunt is substantially equivalent to predicate devices currently being marketed. The marketed predicate devices are identified above. The CTS FloCoil Shunt is substantially equivalent to the predicate devices with regard to intended use, function, physical characteristics, materials and sterilization method.

All necessary testing was performed on the CTS FloCoil Shunt to ensure the product is substantially equivalent to the predicate devices and to ensure that the CTS FloCoil Shunt does not have any differences which have a significant effect on safety and effectiveness.

FUNCTIONAL PERFORMANCE TESTING

Functional testing was conducted on the CTS FloCoil Shunt to ensure that the Shunt would function according to its intended use instructions. All testing conducted confirmed the acceptability of the CTS FloCoil Shunt to perform as intended to help reduce blood in the operative field by temporary occlusion of the artery while providing blood flow distal to the arteriotomy.

BIOCOMPATIBILITY EVALUATION

The biocompatibility testing was conducted on the CTS FloCoil Shunt and Shunt materials to ensure the acceptability of the CTS FloCoil Shunt when used as directed. The CTS FloCoil Shunt and Shunt materials passed the necessary biocompatibility tests.

SUMMARY

As contained in this 510(k) summary, all necessary testing was conducted on the CTS FloCoil™ Shunt to ensure that the device is safe and effective when used in accordance to its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

OCT 30 1997

Re: K970638
CTS MIDCAB Fixed Diameter Coronary Shunt
Regulatory Class: II (Two)
Product Code: DXC
Dated: August 18, 1997
Received: August 21, 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.

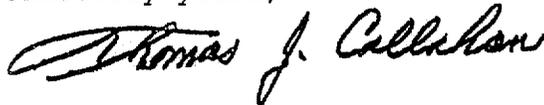
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. Michael J. Billig

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) 594-4648. 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,



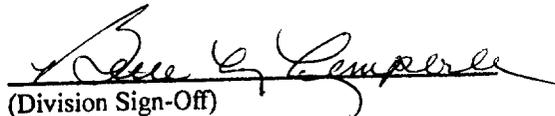
Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardioThoracic Systems, Inc.
CTS FloCoil Shunt
510(k) Premarket Notification

Statement of Indications for Use

The CTS FloCoil Shunt is designed to help reduce blood in the operative field by temporary occlusion of the artery and to provide blood flow distal to the arteriotomy. This FloCoil Shunt is not an implant and is removed prior to completion of the anastomosis.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

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