K983270

SECTION 2

510(k) SUMMARY of SAFETY and EFFECTIVENESS

This summary of the 510(k) premarket notification for the CTS Voyager Quad Cannula is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Summary

CardioThoracic Systems, Inc.
Voyager Quad Cannula
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:
September 16, 1998

DEVICE DESCRIPTION

Classification:
Cardiopulmonary Bypass Vascular Cannula, 21 CFR 870.4210

Trade Name:
CTS Voyager Quad Cannula

Generic/Common Name:
Cardiopulmonary Bypass Vascular Cannula

PREDICATE DEVICES

Cardiopulmonary bypass cannulae manufactured by Medtronic and Sarns.

INTENDED USE

The CTS Voyager Quad Cannula is intended for use in perfusion and occlusion of the ascending aorta during cardiopulmonary bypass. The cannula functions to occlude the ascending aorta when the balloon is inflated. The main lumen of the cannula provides delivery of arterial perfusion. The side lumen allows delivery of cardioplegia to arrest the heart and venting of fluid from the aortic root during cardiac surgery.

PRODUCT DESCRIPTION

The CTS Voyager Quad Cannula is a three lumen cannula with an elastomeric balloon near the distal tip for occluding the ascending aorta in order to partition the aortic root from arterial circulation. The compliant balloon expands to occlude a range of aorta sizes. The large central lumen of the cannula serves to provide arterial perfusion. The side lumen serves two functions: delivery of cardioplegic solution to the aortic root and venting of fluid from the aortic root during cardiac surgery. The remaining lumen serves as a conduit for balloon inflation and deflation. The marker on the cannula outer shaft indicates the insertion depth. The clamp ring provided on the cannula allows the cannula to be fixed into position.

SUBSTANTIAL EQUIVALENCE

The CTS Voyager Quad Cannula is intended for use in perfusion and occlusion of the ascending aorta during cardiopulmonary bypass. The CTS Voyager Quad Cannula is substantially equivalent to other cannulae and catheters currently on the market for use in cardiopulmonary bypass procedures, manufactured by companies such as Research Medical, Inc, (RMI), DLP (Medtronic) and Sarns. The Voyager Quad Cannula is substantially equivalent to these predicate devices in regards to device design, intended use, patient population and anatomical site. Any differences between the Voyager Quad Cannula and its predicate devices do not raise any new issues of safety or effectiveness.

Functional bench testing and animal testing has been conducted and the results of the testing verified that the Voyager Quad Cannula performs as designed and is suitable for its intended use.

SUMMARY

As contained in this 510(k) summary, the CTS Voyager Quad Cannula is substantially equivalent to the predicate device identified in that the Voyager Quad Cannula is substantially equivalent in regards to device design, intended use, patient population and anatomical site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 1999

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

Re: K983270
CTS Voyager™ Quad Cannula
Regulatory Class: II (Two)
Product Code: DWF
Dated: June 18, 1999
Received: June 21, 1999

Dear Mr. Billig:

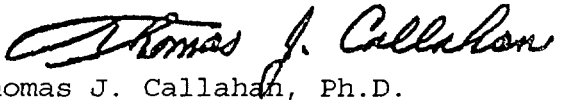
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4648. 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" (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,



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 Voyager™ Quad Cannula
510(k) Premarket Notification

STATEMENT OF INDICATIONS FOR USE

The CTS Voyager Quad Cannula is intended for use in perfusion and occlusion of the ascending aorta during cardiopulmonary bypass. The cannula functions to occlude the ascending aorta when the balloon is inflated. The main lumen of the cannula provides delivery of arterial perfusion. The side lumen allows delivery of cardioplegia to arrest the heart and venting of fluid from the aortic root during cardiac surgery.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983270