OCT 3 1 2003

K033264

510(k) Summary

Date Prepared: September 26, 2003

Submitter:

Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person:

Preeti Jain
Director, Regulatory/Clinical Affairs

Phone: (763) 391-9533
Fax: (763) 391-9603

Device Name and Classification:

Trade Name: Malleable Single Stage Venous Cannula with Carmeda® BioActive Surface
12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40 Fr.

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices: Malleable Single Stage Venous Cannula
K022272

Extracorporeal Circuit with Bio-Active Surface
K8918687

Device Description:
The Malleable Single Stage Venous Cannula with Carmeda® BioActive Surface, is designed for use with cardiopulmonary bypass as a venous drainage cannula. The malleability feature allows the cannulae to be shaped and positioned to meet each customer's specific needs. The Carmeda® BioActive Surface adds a heparin based coating to the cannulae surface.

Indication for Use
These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

Comparison to Predicate Devices
The predicate devices are cannulae with the same design characteristics. The predicate Malleable Single Stage Venous Cannula has the same indications for use.

Summary of Performance Data
In vitro visual, coverage, bioactivity, leaching, functional and biocompatibility testing on Carmeda® coated devices was used to establish the performance characteristics of the modifications of this device from previously marketed devices.

Conclusion
Medtronic Perfusion Systems has demonstrated that the Malleable Venous Cannulae with Carmeda® BioActive Surface are substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

Medtronic Perfusion Systems
c/o Ms. Preeti Jain
Director, Regulatory/Clinical Affairs
7611 Northland Drive N
Brooklyn Park, MN 55428-1088

Re: K033264
Malleable Single Stage Venous Cannula with Carmeda® BioActive Suface
Regulation Number: 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: Class II (two)
Product Code: 74 DWF
Dated: October 2, 2003
Received: October 9, 2003

Dear Ms. Jain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

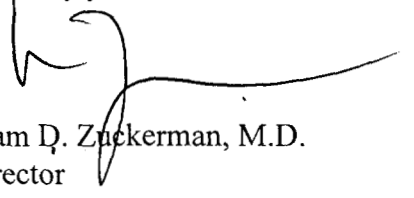
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name:

Malleable Single Stage Venous Cannula with Carmeda® BioActive Surface

Indications for Use:

These cannulae are intended for collection of venous blood from the right side of the heart via the superior and inferior vena cava during cardiopulmonary bypass surgery up to six hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033264