

JUL 2 2003

510(k) Summary

Date Prepared: June 12, 2003

Submitter: Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person: Preeti Jain
Senior Manager, Regulatory Affairs

Phone: (763) 391-9533
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Device Name and Classification:

Trade Name: ULTRAFLEX™ Venous Cannula
23, 29 Fr.

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices: VC2® Venous Cannula
K845045

Bio-Medicus® Femoral Cannula and Introducer
K924642

Extracorporeal Circuit with Bio-Active Surface
K8918687

Device Description:

The ULTRAFLEX™ Venous Cannula is designed for use with cardiopulmonary bypass as a venous drainage cannula. The occluder with a malleable stylet aids in positioning and placement of the cannula. The device is available in 23 and 29 Fr. diameters. The device may also include Carmeda® coating.

Indication for Use

This product is intended for use with cardiopulmonary bypass as a venous drainage cannula.

Comparison to Predicate Devices

The predicate devices are cannulae with the same or similar design characteristics. The predicate cannulae VC2® Two Stage Venous Cannula has the same indications for use. The other predicate cannulae Bio-Medicus® Femoral Cannula and Introducer features the same material and similar introducer configuration and tip design to the ULTRAFLEX™.

Summary of Performance Data

In vitro visual, dimensional, simulated use and functional testing was used to establish the performance characteristic of the modifications of this device from previously marketed devices. In addition coverage, bio-activity and functional testing was performed on Carmeda® coated devices.

Conclusion

Medtronic Perfusion Systems has demonstrated that the ULTRAFLEX™ Venous Cannulae are substantially equivalent to the predicate devices based upon design, test results, and indications for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2003

Medtronic Perfusion Systems
c/o Mr. Preeti Jain
7611 Northland Drive N
Minneapolis, MN 55428-1088

Re: K031827

ULTRAFLEX™ Venous Cannula

Regulation Number: 870.4210

Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, ad Tubing

Regulatory Class: Class II (two)

Product Code: 74 DWF

Dated: June 12, 2003

Received: June 13, 2003

Dear Mr 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.

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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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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:

ULTRAFLEX™ Venous Cannula

Indications for Use:

These cannulae are intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Optional Format 3-10-98)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K031827