K033416

p 1/2

NOV - 5 2003

510(k) Summary

Date Prepared: October 24, 2003

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

Contact Person:
Ronald W. Bennett
Principal Regulatory Affairs Specialist

Phone: (763)-391-9086
Fax: (763) 391-9603

Device Name and Classification:

Trade Name: Select 3D™ Arterial Cannula
22, 24 Fr. with Carmeda® BioActive Surface
Select CAP™ Arterial Cannula
18, 20, 22, 24 Fr. with Carmeda® BioActive Surface

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices:
Arterial Cannula
K840002, K000776, K013013, K010737

Extracorporeal Circuit with BioActive Surface
K891687

Device Description:
The Select 3D™ and Select CAP™ Arterial Cannulae both have clear flexible, thin wall wire-wound PVC bodies with angled, beveled tips. The proximal end of each cannula includes a 3/8" (0.95 cm) vented or non-vented connector with a peel cap. The vented connector allows air to be vented from the cannula before connection to the perfusion line.

The Select 3D™ Arterial Cannula tip has three integrated flutes which help diffuse and disperse blood flow. The cannula body features a tip orientation line indicate direction of the cannula tip during cannulation. Overall cannula length is 11.5" (29.2 cm). It is available in 22 and 24 Fr sizes.

The Select CAP™ Arterial Cannula tips have an integrated pressure monitoring port. The pressure monitoring port on the tip of the cannulae provides the real time capability of accurately measuring central arterial pressure within the aorta. Overall cannula length is 12" (30.5 cm). It is available in 18, 20, 22, and 24 Fr. sizes.

The devices may include a Carmeda® BioActive Surface.

Indication for Use
These cannulae are intended for use in perfusion of the ascending aorta during short term (6 hours or less) cardiopulmonary bypass.

Comparison to Predicate Device
The predicate devices are Select 3D™ and Select CAP™ Arterial Cannulae with the same design characteristics. The predicate cannulae were uncoated. The predicate cannulae have the same indications for use, with the addition of the clarification "(6 hours or less)" for the Select CAP™.

Summary of Performance Data
In vitro visual and functional testing was used to establish the performance characteristic of the materials of these devices after Carmeda® coating. In addition coverage, bioactivity, and leach testing was performed on Carmeda® coated devices.

Conclusion
Medtronic Perfusion Systems has demonstrated that the modified Select 3D™ and Select CAP™ Arterial Cannulae 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

NOV - 5 2003

Medtronic Perfusion Systems
c/o Mr. Ronald W. Bennett
Director, Regulatory/Clinical Affairs
7611 Northland Drive N
Brooklyn Park, MN 55428-1088

Re: K033416
Select 3D™ Arterial Cannula and Select CAP™ Arterial Cannula with Carmeda® BioActive Surface
Regulation Number: 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: Class II (two)
Product Code: 74 DWF
Dated: October 24, 2003
Received: October 27, 2003

Dear Mr. Bennett:

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.

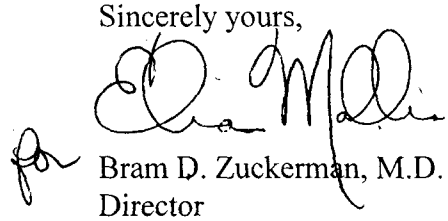
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for 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): K033416

Device Name:

Select 3D™ Arterial Cannula and Select CAP™ Arterial Cannula with Carmeda® BioActive Surface

Indications for Use:

These cannulae are intended for use in perfusion of the ascending aorta during short term (6 hours or less) cardiopulmonary bypass.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033416

(Optional Format 3-10-98)