K061254

510(k) Summary

Date Prepared: May 3, 2006

JUN 23 2006

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

Contact Person: Ronald W. Bennett
Principal Regulatory Affairs Specialist

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Device Name and Classification:

Trade Name: **EOPA 3D™ Arterial Cannula**
Models 78220, 78222, 78320, 783222

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices:
Select 3D Arterial Cannula
K033416, K043179

Device Description:
The EOPA 3D™ Cannulae have clear flexible, thin wall wire-wound PVC bodies with a tapered distal tip. The proximal end of the cannula includes a 3/8" (0.95 cm) vented or non-vented connector. The vented connector allows air to be vented from the cannula before connection to the perfusion line. The EOPA 3D™ Arterial Cannula tip has three integrated flutes which help diffuse and disperse blood flow. The cannula body has multiple depth markings, catalog code, and French size marked. Overall cannula length is 12.5" (31.8 cm). It will be available in 20 and 22 Fr sizes and either uncoated or with a Carmeda coating.

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™ Arterial Cannulae with the same design characteristics. The modified devices use a straight body with the Select 3D Arterial Cannula diffuse flow tip.

Summary of Performance Data
In vitro visual and functional testing was used to establish the performance characteristic of the changes from the predicate devices This includes visual, functional, and blood trauma testing.

Conclusion
Medtronic Perfusion Systems has demonstrated that the modified EOPA 3D™ and 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

JUN 23 2006

Medtronic Perfusion Systems
Ronald W. Bennett
Principal Regulatory Affairs Specialist
7611 Northland Drive N.
Brooklyn Park, MN 55428

Re: K061254
Trade Name: EOPA 3D Arterial Cannula, Models 78220,78222,78320,78322
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula or tubing
Regulatory Class: II (two)
Product Code: DWF
Dated: May 3, 2006
Received: May 4, 2006

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), please contact the Office of Compliance at (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K061254

Device Name:
EOPA 3D™ Arterial Cannula

Indications for Use:

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

Prescription Use	AND/OR	Over-The-Counter Use
X		
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061254