K040173
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MAR 1 9 2004

510(k) Summary

Date Prepared: March 2, 2004

Submitter:

Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person:

Ronald W. Bennett
Principal Regulatory Affairs Specialist

Phone: (763)-391-9086
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Device Name and Classification:

Trade Name: Pediatric Aortic Root Cannula
(18 Gauge)

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices:
Aortic Root Cannulae
K790565, K810548, K831591

Device Description:
The new Pediatric Aortic Root Cannula has a soft, flexible, thin wall, radiopaque tip with a flange and two side holes. The tip is attached to a flexible tapered tube that terminates in a female luer fitting. A stainless steel 18 gauge introducer with needle tip and locking male luer fitting is supplied inside the cannula.

Indication for Use
This cannula is intended for short term use (six hours or less) in conjunction with cardiopulmonary bypass surgery for delivering cardioplegia solutions. The cannula may also be used to aspirate air from the aorta at the conclusion of the bypass procedure.

Comparison to Predicate Device
The predicate devices are Aortic Root Cannulae with the same design characteristics and indications for use. The predicate cannulae had similar design and materials. The new cannula varies from the predicates in tip length and color, in having a ribbed body, in overall length and in featuring an over-molded ABS introducer needle sheath.

Summary of Performance Data
In vitro dimensional and functional testing was used to establish the performance characteristic of the new device. The biocompatibility, sterilization, and packaging were evaluated. Accelerated aged dimensional and functional testing was also performed. All testing passed.

Conclusion
Medtronic Perfusion Systems has demonstrated that the modified Pediatric Aortic Root Cannula (18 Gauge) is 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

MAR 19 2004

Medtronic Perfusion Systems
c/o Mr. Ronald W. Bennett
Principal Regulatory Affairs Specialist
7611 Northland Drive N
Minneapolis, MN 55428-1088

Re: K040173
Pediatric Aortic Root Cannula (18 Gauge)
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: March 3, 2004
Received: March 4, 2004

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 (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) you may obtain. 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

Indications for Use

510(k) Number (if known): K040173

Device Name: Pediatric Aortic Root Cannula

Indications for Use:

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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 K040173 (SM. K)