K034058
p 1/2

JAN 2 9 2004

510(k) Summary

Date Prepared: December 19, 2003

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

Contact Person: Preeti Jain
Senior Manager, Regulatory/Clinical Affairs
Phone: (763)-391-9533
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Device Name and Classification:

Trade Name: Spherical Tip Coronary Ostial Cannula

Model 30011 – 12 French

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices: Coronary Cannula – K821149

Models 30010,30012,30014 – French 10, 12 and 14 French

Device Description:

The Spherical Coronary Artery Ostial Cannula is a line extension of existing Medtronic DLP Coronary Artery Ostial Cannulae and features a uniquely shaped spherical tip. This product is used for the delivery of antegrade cardioplegia solution through the coronary artery ostia during cardiac bypass surgery. The Spherical Coronary Artery Ostial Cannula is intended as an addition to the current line of hand-held cardioplegia perfusion cannulae. Prior products included flanged basket and conforming silicone tips as a means to seal against the ostial opening and deliver cardioplegia.

The distal end of the cannula features a dual-diameter, spherical bulb tip rather than a flanged basket tip for interface to the ostial opening. The released models feature a basket tip with a ring flange that is pressed up against the ostial opening by the physician during cardioplegia delivery. Delivery using the proposed design would, similarly, require the

spherical bulb to be pressed against the ostial opening while solution is dispensed through the smaller tip extension.

Indication for Use

The Spherical Tip Coronary Ostial Cannula is intended for use in conjunction with cardiopulmonary bypass surgery up to six hours or less, for delivery of cardioplegia solutions directly to the coronary arteries.

Comparison to Predicate Device

The Coronary cannula is intended for providing cardioplegia solutions to the coronary artery in conjunction with the cardiopulmonary bypass. The product featured flanged, radiopaque basket tip attached to a malleable stainless steel body. The device is a sterile, non pyrogenic , single use product. The cannulae have a female luer connection site. The malleable handle provides the surgeons the flexibility to bend the cannula to a convenient configuration. The only difference with the submitted model is the tip configuration. The Indications for Use are the same.

Summary of Performance Data

In vitro and functional testing was completed on the modified product to ensure that the product integrity and function is maintained.

Conclusion

Medtronic Perfusion Systems has demonstrated that the Spherical Tip Coronary Ostial Cannula , Model 30011 is substantially equivalent to predicate devices based upon design, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medtronic Perfusion Systems
c/o Ms. Preeti Jain
Senior Manager, Regulatory/Clinical Affairs
7611 Northland Boulevard
Brooklyn Park, MN 55428

Re: K034058
Spherical Tip Coronary Ostial Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Catheter, Cannula and Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: December 23, 2003
Received: December 30, 2003

Dear Ms. Jain:

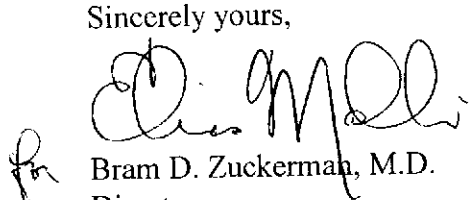
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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), 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

510(k) Number (if known): K034058

Device Name: Spherical Tip Coronary Ostial Cannula

Model : 30011, French Size 12.

Indications for Use:

The Spherical Tip Coronary Ostial Cannula is intended for use in conjunction with cardiopulmonary bypass surgery up to six hours or less, for delivery of cardioplegia solutions directly to the coronary arteries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K034058