K030696 pg 1 of 2

APR 11 2003

510(k) Summary

Date Prepared: March 4, 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
Fax: (763) 391-9603

Device Name and Classification:

Trade Name: Retrograde Coronary Sinus Perfusion Cannula with no Pressure Line

Models 94115NPL, 94725NPL – Manual Inflate
Models 94535 NPL – Auto Inflate

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices: K860149: Venous Perfusion Return Cannula with cuff (14 French, Manual Inflate)
Model 94015

And

K901074: Retrograde Coronary Sinus Perfusion Cannula (15 French, Auto Inflate)
Model 94315

Device Description:
The RCSP cannula consists of kink resistant , silicone or extruded PVC body. The silicone cannula are wire wound. The tip of the cannula has a bevel with side holes or

bullet nose with multi ports to allow the free flow in the coronary sinus. The back of the cannula terminates in a locking female luer. An inflatable balloon is located at the closer to the tip. The inflation assembly for the manual models is located at the back of the cannula body and contains a female slip luer and a one-way valve assembly. These devices are offered with either a guidewire stylet or a solid stylet to help position the cannula.

Indication for Use
These cannula are intended for use during cardiopulmonary bypass surgery for the delivery of Cardioplegia retrograde through the coronary sinus. up to six hours or less.

Comparison to Predicate Device
The predicate devices are existing models of manual and auto inflate RCSP cannula that are identical to the modified device with the exception of the pressure monitoring line. The predicate models also have kink resistant , silicone or extruded PVC body. The silicone cannula are wire wound. The tip of the cannula has a bevel with side holes or bullet nose with multi ports to allow the free flow in the coronary sinus. The back of the cannula terminates in a locking female luer. An inflatable balloon is located at the closer to the tip. The predicate devices have the same indications for use.

Summary of Performance Data
This modification of the device involved removal of a pressure monitoring line that had no effect on the design of the product and its functionality. No product performance testing was necessary for the product.

Conclusion
Medtronic Perfusion Systems has demonstrated that the Retrograde Coronary Sinus Perfusion Cannula with No Pressure Line , Models 94115NPL, 94725NPL and 94535NPL are 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

APR 11 2003

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

Re: K030696
Retrograde Coronary Sinus Perfusion Cannula without Pressure Monitoring Lumen
Models 94115NPL, 94725NPL – Manual Inflate
Models 94535NPL – Auto Inflate
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: April 3, 2003
Received: April 4, 2003

Dear Mr. Jain:

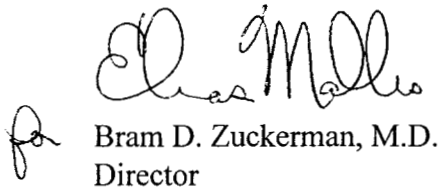
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May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



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): K030696

Device Name: Retrograde Coronary Sinus Perfusion Cannula without Pressure Monitoring Lumen

Models 94115NPL, 94725NPL – Manual Inflate

Models 94535NPL – Auto Inflate

Indications for Use:

The Retrograde Coronary Sinus Perfusion cannula is intended for use during cardiopulmonary bypass surgery for the delivery of cardioplegia retrograde through the coronary sinus up to six hours or less.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109) K030696