K994177

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APR 2 7 2000

Medtronic

510(k) Summary

[As Required by *21 CFR 807.92*]

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Date Summary Prepared: December 7, 1999

Trade Name of Device: Medtronic AortoCoronary Shunt and separately packaged Arteriotomy Cannulae

Common Name of Device: Cardiovascular cannula and tubing

Classification Name of Device: "Cardiopulmonary bypass vascular cannula and tubing", Class II at *21 CFR 870.4210*

Predicate Substantially Equivalent Devices:

Medtronic DLP Aortic Root Cannula
Class II at *21 CFR 870.4210*

Medtronic DLP Y-Type Coronary Perfusion Adapter
Class II at *21 CFR 870.4210*

Medtronic DLP Coronary Cannula
Class II at *21 CFR 870.4210*

Description of Device: The Medtronic AortoCoronary Shunt includes an Aortic Root Cannula Assembly, a Y-Tubing Connector Assembly and a set of Arteriotomy Cannulae (2 mm, 3 mm and 4 mm sizes). The Arteriotomy Cannula Assemblies are also available separately for user convenience. The user assembles the components into the final product configuration immediately prior to use. The assembled device diverts oxygenated, arterial blood from the patient's aorta directly to one or two coronary arteries, thereby providing perfusion of an ischemic area of the heart during cardiac surgical procedures

Intended Use of Device: These devices are intended for the perfusion of anticoagulated arterial blood to an ischemic area of the heart.

Comparison to Predicate Devices:

The Aortic Root Cannula Assembly used in the new Medtronic AortoCoronary Shunt is identical to the predicate Medtronic DLP 10014 Aortic Root Cannula except for the substitution of a more flexible material that is used to fabricate the cannula body. The Y-Tubing Connector Assembly used in the new Medtronic AortoCoronary Shunt is very similar to the predicate Medtronic DLP 10004 Y-Type Coronary Perfusion Adapter except for material substitutions, which permit increased flexibility of this assembly as well. Finally the Arteriotomy Cannula Assemblies used in the new Medtronic AortoCoronary Shunt are substantially equivalent to the predicate Medtronic DLP 30010 and 30012 Coronary Cannula in that both the new and predicate devices are intended to deliver protective fluid (blood or cardioplegia solution) to myocardial tissue via direct cannulation of the coronary arteries.

Summary of Non-Clinical Performance Data:

Material biocompatibility testing was conducted in accordance with the *ISO 10993-1* standard. Under this standard the AortoCoronary Shunt and Arteriotomy Cannulae are categorized as externally communicating devices in contact with circulating blood for a limited (<24 hour) contact duration. The battery of biocompatibility tests performed yielded negative (non-toxic) results in Cytotoxicity (MEM Elution Method), Sensitization (Guinea Pig Maximization Method), Intracutaneous Reactivity (in rabbits), Acute Systemic Toxicity (in mice), Genotoxicity (Ames *Salmonella typhimurium / Escherichia coli* Mutation Reversion Method) and Hemocompatibility (material-mediated Hemolysis and Thrombogenicity) assessments.

Tensile and hydrostatic burst testing were performed on all segments of the fully assembled AortoCoronary Shunt. These tests yielded acceptable results. Resistance to fluid flow, determined by measuring the rate of flow from the end of the device as a function of the fluid pressure head at the inlet of the device, was assessed as well. This parameter was evaluated for both the Arteriotomy Cannulae alone as well as for the fully assembled AortoCoronary Shunt. These tests demonstrated that the product is capable of delivering blood to target coronary arteries at flow rates that are higher than those that are normally observed in those coronary arteries. Finally the resistance of the product to kinking and damage due to clamping the sections of tubing was assessed. This testing yielded acceptable results as well.

Conclusions of Non-Clinical Tests:

The results of the non-clinical tests summarized above support an assertion that the Medtronic AortoCoronary Shunt and Arteriotomy Cannulae are as safe and effective as the three predicate legally marketed medical devices itemized above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2000

Mr. James Balun
Principal Product Regulations Manager
Medtronic Cardiac Surgical Products
620 Watson SW
Grand Rapids, MI 49504

Re: K994171/S1
Medtronic AortoCoronary Shunt and Arteriotomy Cannulae
Regulatory Class: II
Product Code: DWF
Dated: March 27, 2000
Received: March 28, 2000

Dear Mr. Balun:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994171

Device Name: Medtronic AortoCoronary Shunt and separately packaged Arteriotomy Cannulae

Indications For Use:

These devices are intended for the perfusion of anticoagulated arterial blood from the aorta to coronary vessels to supply an ischemic area of the heart during beating heart CABG procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K994171

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)