DEC 0 4 2001

K013013

Summary of Safety and Effectiveness Information

DEC 0 4 2001

510(k) Summary

[As Required by *21 CFR 807.92*]

Submitter: Roger Brink
Medtronic Cardiac Surgical Products
620 Watson SW
Grand Rapids, MI 49504

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Date Summary Prepared: September 4, 2001

Trade Name of Device: Medtronic DLP Arterial Cannulae modified with 3D Tip – 22 Fr.

Common Name of Device: Cardiovascular cannula

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

Predicate Substantially Equivalent Devices: Medtronic DLP Arterial Cannulae, Class II at *21 CFR 870.4210,* Curved Tip Models cleared under 510(k) Number K840002, and 24 Fr. 3D Tip Models cleared under 510(k) Number K000776.

Description of Device: The Medtronic DLP Arterial Cannulae with 3D Tip represent modified versions of existing Medtronic DLP Arterial Cannulae. The proposed change involves the incorporation of a baffled tip design into the 22 Fr. cannula. This baffled tip imparts a more diffuse pattern of blood flow exiting from the cannula tip than exists with the existing open tip cannula design.

Intended Use of Device: These cannulae are intended for the perfusion of the ascending aorta during short-term (6 hours or less) cardiopulmonary bypass.

Comparison to Existing Predicate Devices

The Medtronic DLP Arterial Cannulae with 3D Tip – 22 Fr. are substantially equivalent to existing Medtronic DLP Arterial Cannulae. The existing cannulae have been modified to include a baffled tip, which features side exit holes and scoop-shaped exit ports on the outside of the tip surface. The indications for use for both the existing and modified devices are identical, and the addition of a baffled tip feature does not represent a change to the fundamental scientific technology of the devices.

Summary of Non-Clinical Performance Data

Material biocompatibility testing was conducted in accordance with the ISO 10993-1 standard. Under this standard these cannulae are categorized as externally communicating devices in contact with circulating blood for a limited (<24 hour) contact duration.

An *in vitro* assessment of the dynamic hemolytic properties of the cannulae was also performed. Short circuits containing 1000 ml of freshly collected, heparinized bovine blood were constructed. The blood was circulated through test circuits which included the 22 Fr. 3D Tip model and competitive comparator models. Rates of hemolysis that were comparable to those measured for the comparator cannulae were observed for the modified device as well.

Conclusions of Non-Clinical Tests

The results of the non-clinical tests summarized above support an assertion that the Medtronic DLP Arterial Cannula 22 Fr. modified with a 3D Tip are as safe and effective as the existing Medtronic DLP Arterial Cannulae.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2001

Mr. Roger W. Brink
Director RA/QA
Medtronic Cardiac Surgical Products
620 Watson SW
Grand Rapids, MI 49504-6393

Re: K013013
Trade Name: Medtronic DLP Arterial Cannulae with 3D Tip - 22 Fr
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiovascular Bypass Vascular Catheter
Regulatory Class: II (two)
Product Code: DWF
Dated: September 4, 2001
Received: September 7, 2001

Dear Mr. Brink:

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.

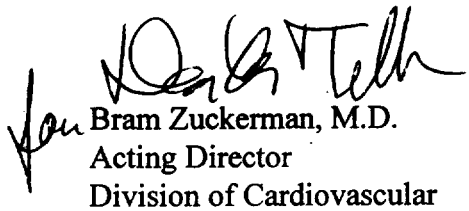
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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). 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,



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

Enclosure

510(k) Number (if known): K013013

Device Name: Medtronic DLP Arterial Cannulae with 3D Tip – 22 Fr.

Indications for Use:

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

This Indication for Use is identical to the predicate device.
Medtronic DLP Arterial Cannulae with 3D Tip – 24 Fr.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013013

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