

K 991066



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SEP 14 1999

510(k) Summary

[As Required by 21 CFR 807.92]

Submitter: James Balun
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Date Summary Prepared: March 26, 1999

Trade Name of Device: Medtronic DLP Arterial Cannula Family (Including Descending Arch and Elongated One-Piece Arterial Models)

Common Name of Device: Cardiovascular cannula

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

Predicate Substantially Equivalent Device: Medtronic DLP Arterial Cannula Family,
Cleared under 510(k) Number K880421 on April 28, 1988,
Class II at 21 CFR 870.4210

Description of Device: These Medtronic DLP Arterial Cannulae feature a thin-wall cannula body with a beveled tip which is fabricated from either polyurethane or wire-reinforced polyvinyl chloride. The proximal end of the cannula terminates in a barbed 3/8" connector. A plastic, blunt tip introducer with a porous plug is provided to aid in insertion of the cannula and prevent excessive blood loss during priming. The introducer includes a port which enables insertion along a 0.038" guidewire.

510(k) Summary
Medtronic DLP Arterial Cannula Family



Intended Use of Device: These products are intended for use with cardiopulmonary bypass as arterial return cannulae.

Comparison to Predicate Devices:

No change to the intended use of these cannulae is being implemented in conjunction with the proposed device modifications. The proposed modifications include:

- (1) Blunting, i.e., increasing the radius, of the tip of the introducer; and
- (2) Revisions to the Warnings section of the Directions for Use.

Summary of Non-Clinical Performance Data:

A laboratory assessment of the force which must be applied to the cannula introducer in order to penetrate an aqueous, semi-solid matrix was performed. This assessment verified that increasing the radius of the introducer tip significantly increased the amount of force required to penetrate this test material.

Conclusion of Non-Clinical Testing:

The result of this laboratory test supports an assertion that the Medtronic DLP Arterial Cannula Family which has been modified as described above is as safe and effective as the original cannula which was cleared for marketing in April 1988.



Mr. James Balun
Principal Product Regulation Manager
Medtronic, Inc.
Medtronic DLP
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Grand Rapids, MI 49501-0409

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1999

Re: K991066
Medtronic DLP Arterial Cannula Family (DLP Descending Arch Arterial Cannula, product codes 70321, 70324, 71321, and 71324, and DLP Elongated One-Piece Arterial Cannula, product codes 77420, 77422, 77520, and 77522)
Regulatory Class: II
Product Code: DWF
Dated: July 16, 1999
Received: July 19, 1999

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.

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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), or 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 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991066

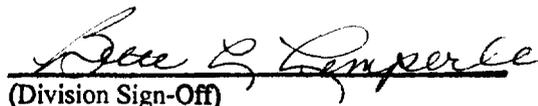
Device Name: Medtronic DLP Arterial Cannula Family (Including Descending Arch and Elongated One-Piece Models)

Indications For Use:

This product is intended for use with cardiopulmonary bypass as an arterial return cannula.

(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 K991066

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____