

APR 17 2000

K 993677

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510(k) Summary

Submitter: Medtronic DLP
620 Watson, S.W.
Grand Rapids, Michigan 49504

Contact: Michael Hingson

Telephone Number: 616.356.5518
Facsimile Number: 616.242.5214

Date 510(k) Summary Prepared: October 29, 1999

Trade Name of Device: Medtronic ClearView® Intravascular Arteriotomy Shunt

Common Name of Device: Cardiopulmonary bypass vascular catheter, cannula or tubing (21 CFR 870.4210)

Substantially Equivalent Predicate: Chase Blood Vessel Shunt
Class II at 21 CFR 870.4210

Description of Device: The Medtronic ClearView® Intravascular Arteriotomy Shunt is a temporary arterial shunt for use during coronary artery bypass grafting procedures (CABG). The device features two teardrop shaped bulbs over-molded onto the ends of a flexible tubular shaft. The device is provided in nine sizes. A tag attached to each device identifies size. The device is radiopaque.

Intended Use: These shunts are intended for use to shunt blood by the arteriotomy anastomosis site while the surgeon is making the anastomosis.

Comparison to Predicate Device:

The predicate to which substantial equivalence is claimed is the Chase Blood Vessel Shunt. The ClearView Shunt and the Chase Blood Vessel Shunt are similar in design; manufacturing materials, flow characteristics and physical dimensions. The predicate device's intended use is to internally shunt blood vessels during anastomosis.

Summary of Non-Clinical Performance Data:

Biocompatibility testing was performed in accordance with *ISO 10993-1: Biological evaluation of medical devices-- Part 1: Evaluation and Testing*. The Medtronic ClearView® Intravascular Arteriotomy Shunt is classified under externally communicating devices coming in contact with circulating blood with contact duration of ≤ 24 hours. The device tested negative for: cytotoxicity, hemolysis, sensitization, systemic toxicity and intracutaneous toxicity.

Performance testing of the device included flow curve, radiopacity and tensile strength testing.

Flow Curve

Flow characterization testing was performed to assure that the ClearView Shunt would perform as described in the device's indications for use. Identical sizes of the Medtronic ClearView Shunt and the predicate device were tested on a flow bench unit. The flow bench unit generates flow curves by plotting pressure differential (mm/Hg) against water flow rate (mL/min.). Water was directed through the lumen of each device at flow rates ranging from 0-200mL/min., or as needed to characterize the flow of each shunt at and below 80mm/Hg. Flow curves generated from the tested devices demonstrated the ClearView Shunt to have flow curves equivalent to or better than the predicate device. Tests on other sizes of the ClearView Shunt demonstrated measurable flows for all devices tested.

Radiopacity Testing

The ClearView Shunt was tested to determine if the radiopaque components of the device would be visible by radiographic imaging. ClearView Shunts were placed atop a phantom chest device. The phantom chest simulates the tissue and fluid densities that would be present in a closed adult chest. Processed radiographs of the ClearView Shunts on the phantom chest device revealed all ClearView test shunts could be identified.

Tensile Strength Testing

Tensile strength testing of the ClearView Shunt was performed to assure the device would be able to withstand the estimated physical forces it is expected the device would be subjected to when used as indicated. Various attachments and components of the ClearView Shunt were subjected to pull forces exceeding that which would be expected during normal usage (i.e., as indicated). All shunt components and attachments passed tensile strength test requirements.

Conclusions of Non-Clinical Performance Testing

Non-clinical performance testing of the Medtronic ClearView® Intravascular Arteriotomy Shunt indicates the device is safe and effective for its indicated use and the product is substantially equivalent to the claimed predicate Chase Blood Vessel Shunt.

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**
[As required by 21 CFR 807.87(j)]

I certify that in my capacity as Principal Product Regulations Manager at Medtronic DLP, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.


Signature

James Balun
Typed Name

10/29/99
Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2000

Mr. Michael Hingson
Product Regulation Manager
Medtronic Cardiac Surgical Products
620 Watson SW
Grand Rapids, MI 49504

Re: K993677
Medtronic ClearView® Intravascular Arteriotomy Shunt
Regulatory Class: II
Product Code: DWF
Dated: March 3, 2000
Received: March 6, 2000

Dear Mr. Hingson:

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.

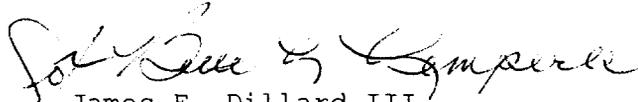
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Michael Hingson

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

510(k) Number (if known): K 993677

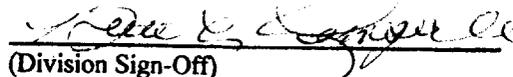
Device Name: Medtronic ClearView® Intravascular Arteriotomy Shunt

Indications For Use:

These shunts are intended for use to shunt blood by the arteriotomy anastomosis site while the surgeon is making the anastomosis.

(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 K 993677

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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