510(K) SUMMARY

Date Prepared:	September 06, 2005
Date Revised:	December 28, 2005
Submitter:	Medtronic, Inc. Cardiac Rhythm Management 7000 Central Avenue NE Minneapolis, MN 55432
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Proprietary Name:	6248VAL Adjustable Valve
Common Name:	Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.
Device Classification:	Class II, 21 CFR 870.4290
Product Code:	DTL

Summary of Substantial Equivalence

The intended use, design, function, materials and method of operation, of the 6248VAL Adjustable Valve are substantially equivalent with regard to these features, to the following predicate devices:

- Medtronic Adjustable Hemostasis Valve (model 6218VAL) – K012083 and K012130 cleared August 28, 2001.
- Guidant Rapido Cut-A-Way Rotating Hemostasis Valve – K031688 cleared July 2, 2003
- Angeion Y-Adaptor with Touhy-Borst Valve – K895580 cleared April 30, 1990

Device Description

The 6248VAL Adjustable Valve is a single use valve designed to reduce blood loss during percutaneous catheter procedures. The valve sealing diameter is adjustable so it may be tightened or loosened to provide an appropriate seal around devices such as leads, guidewires, and catheters, which are passed through the main valve port. Blood flow through the valve is reduced as the valve is closed.

Indications for Use

The Medtronic model 6248VAL adjustable valve is intended to minimize blood loss during percutaneous catheter procedures used to place cardiac leads and implant accessories such as guide wires and subselecting catheters.

Technological Characteristics

Mechanical method of operation, sealing mechanism and packaging materials are substantially equivalent to the predicate devices referenced.

Summary of Testing

Device verification testing was performed to demonstrate the valve meets established performance criteria and to support equivalency to the referenced predicate devices. Visual, mechanical and performance testing was completed. All design and performance requirements were met.

Biocompatibility testing consistent with ISO 10993-1: 2003. "Biological Evaluation of Medical devices – Part 1: Evaluation and Testing" was also conducted.

The 6248VAL Adjustable Valve will be sterilized using a validated gamma radiation process.

Conclusion

Medtronic considers the 6248VAL Adjustable Valve to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2006

Medtronic, Inc.
c/o Ms. Michelle Nivala
Regulatory Affairs Specialist
7000 Central Avenue NE
Minneapolis, MN 55432

Re: K052459
6248VAL Adjustable Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II (Two)
Product Code: DTL
Dated: December 5, 2005
Received: December 6, 2005

Dear Ms. Nivala:

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Donna R. Richner

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052459

Device Name: 6248VAL Adjustable Valve

Indications for Use: The Medtronic model 6248VAL adjustable valve is intended to minimize blood loss during percutaneous catheter procedures used to place cardiac leads and implant accessories such as guide wires and subselecting catheters.

Prescription Use **X** AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vehmeyer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052459