K082873

FEB - 6 2009

510(k) Summary

Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923-5186
Contact Person:	Tara N. Turney, RAC Regulatory Affairs Specialist Phone: 978-739-6654 Fax: 978-777-0390 tara.n.turney@medtronic.com
Date Prepared:	September 26, 2008
Trade Name:	Medtronic Angiographic Guide Wires
Common Name:	Angiographic Guide Wires
Classification Name:	Catheter Guide Wire
Predicate Device:	Medtronic Angiographic Guide Wires, Pre-Amendment, K772021 and K780438
Device Description:	The Medtronic Angiographic Guide Wires are stainless steel guide wires that are constructed of an inner core wire, a safety wire and an outer spring coil. They have a polytetrafluoroethlyene coating and are available in a variety of configurations of length, diameter and other features.
Statement of Intended Use:	The Medtronic Angiographic Guide Wires are indicated for percutaneous entry into vessel using the Seldinger technique.
Summary of Technological Characteristics:	There are no changes to the technological characteristics of the Medtronic Angiographic Guide Wires with this submission; characteristics such as product performance, design and intended use have remained the same.
Summary of Non-clinical Data:	The proposed Medtronic Angiographic Guide Wires has successfully passed all applicable testing.
Conclusion from Data:	Medtronic has demonstrated that the Angiographic Guide Wires are substantially equivalent to the predicate device based upon indications for use, design, test results and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

Medtronic Vascular
c/o Ms. Tara N. Turney, RAC
Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923

Re: K082873
Trade/Device Name: Medtronic Vascular Angiographic Guide Wires
Common Name: Catheter cannula
Regulation Number: 21 CFR 870.1330
Regulatory Class: II
Product Code: DQX
Dated: December 29, 2008
Received: January 2, 2009

Dear Ms. Turney:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchner

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): K082873

Device Name: Medtronic Angiographic Guide Wires

Indications for Use:

- The Medtronic Angiographic Guide Wires are indicated for percutaneous entry into vessel using the Seldinger technique.

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)

Susan R. Mitchell
(Division Sign-Off)
Division of Cardiovascular Devices

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