September 15, 2021

Medtronic Vascular
Karen Brozowski
RA Manager
37a Cherry Hill Dr.
Danvers, Massachusetts 01923

Re: K061958
Trade/Device Name: Medtronic Export XT Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Karen Brozowski:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 5, 2006. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.09.15 09:18:24 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2006

Medtronic, Inc.
c/o Ms. Karen A. Brozowski
Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923

Re: K061958
Medtronic® Export® XT Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: August 15, 2006
Received: August 16, 2006

Dear Ms. Brozowski:

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,

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): K061958

Device Name: Medtronic Export® XT Catheter

Indications for Use:

The Medtronic Export® XT Catheter is indicated for:

- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and
- To subselectively infuse/deliver diagnostics or therapeutics agents with or without vessel occlusion.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 Devices
510(k) Number K061958

K061958

510(k) Summary

Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923 USA
Contact Person:	Karen A. Brozowski Regulatory Affairs Manager 978.739.4143 978.777.0390 Karen.a.brozowski@medtronic.com
Date Prepared:	July 7, 2006
Trade Name:	Medtronic® Export® XT Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter
Predicate Device:	Export Aspiration Catheter (K040869)
Device Description:	The Medtronic Export XT Catheter is a dual lumen catheter used for the aspiration of thrombus and/or debris from a vascular site. The Medtronic Export XT Catheter may also be used for the infusion of diagnostic or therapeutic agents to a desired vascular site.
Statement of Intended Use:	The Medtronic Export XT Catheter is indicated for: Removal/aspiration of embolic material thrombus/debris) from vessels of the arterial system, and to subselectively infuse/deliver diagnostics or therapeutics agents with or without vessel occlusion.
Summary of Technological Characteristics:	• **Distal Dual Lumen:** Small lumen provides conduit for delivery over a 0.014" guidewire, or equivalent, and large lumen provides conduit for aspiration of embolic material. • **Radiopaque Markerband:** Embedded in the distal tip to facilitate placement by fluoroscopy • **External Coating:** Provides lubricious external surface for ease of delivery through the vasculature. • **Wire Braided Shaft:** Provides a balance of stiffness and compliance for delivery of the catheter to the intended

SEP - 5 2006

Summary of Technological Characteristics (continued):	therapy site. • **Luer Hub:** Provides a connection fitting to mate the shaft with the aspiration line. • **Strain Relief:** Provides a stiffness transition between the shaft and the rigid hub to reduce likelihood of shaft kink.
Summary of Non-clinical Data:	The proposed Medtronic Export® XT Catheter has successfully passed all design verification and validation testing.