May 20, 2021

Medtronic Vascular
Tara Turney
Regulatory Affairs Specialist
37a Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K081573
Trade/Device Name: Medtronic Export AP Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Tara Turney:

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 June 27, 2008. 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: 2021.05.20 10:12:54 -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

JUN 27 2008

Medtronic Vascular
c/o Ms. Tara N. Turney
Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923-5186

Re: K081573
Trade Name: Medtronic Export® AP Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: June 4, 2008
Received: June 5, 2008

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) 276-0120. 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) 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. Bachman

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): K081573

Device Name: Medtronic Export® AP Catheter

Indications for Use:

The Medtronic Export® AP Catheter is indicated for:

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

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 Strohmeier

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081573

K081573

510(k) Summary JUN 27 2008

Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923-5186
Contact Person:	Tara N. Turney Regulatory Affairs Specialist Phone: 978-739-6654 Fax: 978-777-0390 tara.n.turney@medtronic.com
Date Prepared:	June 4th, 2008
Trade Name:	Medtronic Export® AP Aspiration Catheter
Common Name:	Aspiration Catheter
Classification Name:	Embolectomy Catheter
Predicate Device:	Medtronic Export® XT Aspiration Catheter K061958
Device Description:	The Medtronic Export® AP Aspiration Catheter is a dual lumen catheter used for aspiration of thrombus and/or debris from a vascular site. The Medtronic Export® AP may also be used for the infusion of diagnostic or therapeutic agents to a desired vascular site.
Statement of Intended Use:	The Medtronic Export® AP Aspiration Catheter is indicated for: • Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and • To subselectively infuse/deliver diagnostics or therapeutic agents with or without vessel occlusion.
Summary of Technological Characteristics:	• Distal Dual Lumen: The smaller of the two lumens provides a conduit for delivery over a 0.014" guidewire, or equivalent, and the larger 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.
- Wire Braided Shaft: Provides a balance of stiffness and compliance for delivery of the catheter to the intended therapy site.
- Luer Hub: Provides a connection fitting to mate the shaft with the aspiration line.

Summary of Non-clinical Data: The proposed Medtronic Export® AP Aspiration Catheter has successfully passed all design verification and validation testing.

Conclusion from Data: Medtronic has demonstrated that the Export® AP Aspiration Catheter is substantially equivalent to the predicate device based upon indications for use, design, test results and fundamental scientific technology.