DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Vascular
Colleen Mullins
Principal Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923-5186

Re: K152335
Trade/Device Name: Export Advance™ Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: Aug 17, 2015
Received: Aug 19, 2015

Dear Ms. Mullins:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for 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: K152335

Device Name: Medtronic Export Advance™ Aspiration Catheter

Indications for Use:

The Export Advance™ Aspiration Catheter is indicated for:

- Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and
- To sub selectively 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 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Special 510(k) Summary

Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923-5186
Contact Person:	Colleen Mullins Principal Regulatory Affairs Specialist Phone: (978) 739-3267 Fax: (978) 739-3280
Alternate Contact	Fred Boucher Director of Regulatory Affairs Phone: (978) 739-3116 Fax: (978) 750-8204
Date Prepared:	August 17th , 2015
Trade Name:	Export Advance™ Aspiration Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Embolectomy Catheter Class II per 21 CFR 870.5150, Product Code DXE
Predicate Devices:	K130536 - Medtronic Vascular Export® Advance Aspiration Catheter.
Device Description:	The Export Advance™ Aspiration Catheter is a dual lumen catheter used for the aspiration of thrombus and/or debris from a vascular site. The Export Advance™ may also be used for the infusion of diagnostic or therapeutic agents to a desired vascular site.
Statement of Intended Use:	The Export Advance™ Aspiration Catheter is indicated for: • Removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system, and • To sub selectively infuse/deliver diagnostics or therapeutics agents with or without vessel occlusion.

Comparison to the predicate devices

The Export Advance™ Aspiration Catheter represents a change to the dual lumen section (micro-lumen section)

Summary of Technological Characteristics:

The Export Advance™ includes the following features:

i. Removable Stylet
ii. Luer Hub
iii. Strain Relief
iv. Inner Liner
v. Braid Wire
vi. Proximal Shaft
vii. Distal Shaft (Dual Lumen/Oversleeve)
viii. Soft Tip
ix. Microlumen (wire lumen)
x. Distal Tip
xi. Marker band
xii. Hydrophilic lubricous coating

Summary of Non-clinical Data:

Design verification (bench) testing qualification conducted in accordance with the recommendations presented from the relevant FDA guidance to demonstrate that the subject device Export Advance™ Aspiration Catheter has met the acceptance criteria and performance similar to the predicate device.

Design Verification Testing: Given that the only difference between the modified design for the subject device and the commercially available design of the predicate device is the dual lumen section, only attributes impacted by the design modification were tested. The design verification (bench) testing was performed based upon the subject device performance specifications. The tests performed for bench testing included:

1. Profile Dimensions (Major & Minor Profile)
2. Microlumen Tear
3. 2D Track and Lesion Cross

Biocompatibility Testing (GLP): The materials, packaging and configuration of the subject device is not changing as a result of the dual lumen design change. The microlumen sleeve material is changing from Pebax 4033 to Aesno MED Nylon 12(AV100) This material is already in use on the Export Advance

within the proximal outer jacket component, distal cuff, and cuff extension. Based on this information there is no requirement for additional biocompatibility testing. Existing biocompatibility data previously performed on the subject device will apply to the proposed device.

Pursuant to the ISO 10993-1:2009/AC: 2010- *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;* and 21 CFR 58 -*Good Laboratory Practice for Nonclinical Laboratory Studies;* Medtronic Vascular has concluded full biocompatibility testing on the predicate device.

1. Cytotoxicity
2. *In vitro* Hemolysis
3. Systemic Toxicity
4. Sensitization
5. C3a Complement Activation
6. Sc5b9 Complement Activation
7. ISO Intracutaneous Reactivity
8. USP Material Mediated Pyrogen Study
9. *In vivo* Thromboresistance

No new safety or effectiveness issues were raised during the testing. The bench testing qualification and biocompatibility testing demonstrated that the subject device Export Advance™ Aspiration Catheter is substantially equivalent to the predicate device.

Summary of Clinical Data: No clinical investigation has been performed on the subject device Export Advance™ Aspiration Catheter.

Conclusion from Data: Medtronic Vascular has demonstrated that the subject device Export Advance™ Aspiration Catheter is substantially equivalent to the predicate device.