DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 22, 2016

Medtronic Vascular, Inc.
% Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K162384
Trade/Device Name: TrailBlazer Angled Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 12, 2016
Received: August 25, 2016

Dear Mr. Job:

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,

Brian D. Pullin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162384

Device Name
TrailBlazer™ Angled Support Catheter

Indications for Use *(Describe)*
The TrailBlazer™ angled support catheters are percutaneous, single lumen catheters designed for use in the peripheral vascular system. The TrailBlazer™ angled support catheters are intended to guide and support a guide wire during access of the vasculature, to allow for guide wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

TrailBlazer™ Angled Support Catheter

510(k) Summary	This 510(k) Summary is being submitted per the requirements of 21 C.F.R § 807.92.
Applicant	Medtronic Vascular, Inc.
Submitter	Medtronic Vascular, Inc. (formerly d.b.a ev3 Inc.) 3033 Campus Drive Plymouth, MN 55441 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	David Robertson Senior Regulatory Affairs Specialist
Date Prepared	August 12, 2016
Device Trade Name	TrailBlazer™ Angled Support Catheter
Device Common Name	Catheter, Support
Classification Name	Catheter, Percutaneous (21 CFR 870.1250), Product Code DQY
Classification Panel	Cardiovascular
Predicate Devices	ev3 TrailBlazer™ Support Catheter (K092299) Cook Medical CXI® Support Catheter (K122796)
Indication for Use	The TrailBlazer angled support catheters are percutaneous, single lumen catheters designed for use in the peripheral vascular system. The TrailBlazer angled support catheters are intended to guide and support a guide wire during access of the vasculature, to allow for guide wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Device Description

The TrailBlazer™ angled support catheter is an over-the-wire (OTW) single lumen catheter with a tapered angled distal tip. The catheter system is compatible with 0.36 mm (0.014in.), 0.46 mm (0.018 in.), or 0.89 mm (0.035 in.) guidewires. The support catheter has working lengths of 65 cm, 90 cm, 135 cm, and 150 cm depending on the model. All models are compatible with a 4 Fr introducer sheath.

The manifold provides proximal access to the lumen which transitions to the catheter shaft and terminates at the angled distal tip. The lumen is used to pass the catheter over a guidewire. The manifold is constructed from elastomer and molded to the catheter proximal shaft. The guidewire compatible diameter and length are marked on the strain relief that is clipped to the manifold post molding. The multi-layer elastomer catheter shaft is designed with a stainless steel braided mesh. Three radiopaque markers starting at the distal tip aid in positioning the catheter. The distal tip of the catheter is molded to a predetermined angle to optimize vessel sub-selection with a guidewire. The distal 40cm portion of the catheter is coated with a hydrophilic coating. Finished catheters are packaged in hoops, sealed in pouches and provided in 5-pack cartons with an IFU.

Technological Characteristics

The TrailBlazer™ angled support catheter has the following similarities to the predicate TrailBlazer and the Cook Medical CXI devices:

- Similar fundamental scientific technology
- Similar operating principle
- Similar flow rate
- Similar crossing profiles
- Similar catheter lengths

The primary predicate TrailBlazer support catheter (straight tip) design has been modified to include an angled tip that improves guide wire directional control during access of the vasculature. The TrailBlazer angled support catheter is constructed with a multi layered stainless steel braided shaft design similar to the secondary predicate Cook Medical CXI support catheter design, intended to increase torque control at the distal tip.

Performance data

To demonstrate substantial equivalence of the proposed TrailBlazer™ Angled Support Catheter to the predicate devices, bench testing was performed:

- Dimensional Verification
- Simulated Use

- Catheter Bond Strength
- Tip Pull Test
- Flexibility and Kink Test
- Torque Strength and Rotational Control
- Radiopacity
- Catheter Body Burst
- Coating Integrity, and Particulate Evaluation
- Contrast Media Flow rate
- Packaging and Shelf Life
- Biocompatibility (cytotoxicity, sensitization, irritation, systemic toxicity, pyrogen, hemolysis, thromboresistance, complement activation, partial thromboplastin time, platelet and leukocyte counts, mutagenicity, lymphoma and micronucleus)

All testing was performed in accordance with recognized standards. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.

Conclusion

Based on the intended use, technological characteristics, and performance testing, Medtronic believes the TrailBlazer™ Angled Support Catheter is substantially equivalent to the ev3 TrailBlazer™ Support Catheter (K092299) and Cook Medical CXI® Support Catheter (K122796).