



Food and Drug Administration
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August 19, 2016

Medtronic Vascular
Nisarg Shah
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Danvers, Massachusetts 01923

Re: K161287

Trade/Device Name: DxTerity, DxTerity TRA, DxTerity Angio-Kit, DxTerity EZ-Pak,
DxTerity TRA Angio-Kit, DxTerity TRA EZ-Pak

Regulation Number: 21 CFR 870.1200

Regulation Name: Diagnostic Intravascular Catheter

Regulatory Class: Class II

Product Code: DQO

Dated: July 21, 2016

Received: July 22, 2016

Dear Nisarg Shah:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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" (21 CFR 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,


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

Indications for Use

510(k) Number (if known)

K161287

Device Name

DxTerity™ Diagnostic Angiography Catheters (DxTerity™, DxTerity™Angio-Kit, DxTerity™ EZ-Pak, DxTerity™ TRA, DxTerity™ TRA Angio-Kit, DxTerity™ TRA EZ-Pak)

Indications for Use (Describe)

The diagnostic catheter is indicated for cardiac and vascular procedures. It is designed to deliver radiopaque media, guidewires, and therapeutic agents to selected sites in the vascular system. The different configurations of the diagnostic catheter are designed to be used in arteries from access sites such as the radial, brachial, and femoral arteries.

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 – K161287

Submitter: Medtronic Vascular
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Date Prepared: August 19, 2016

Trade Name(s): DxTerity™
DxTerity™ Angio-Kit
DxTerity™ EZ-Pak™
DxTerity™ TRA
DxTerity™ TRA Angio-Kit
DxTerity™ TRA EZ-Pak™

Common Name: Catheter, Intravascular, Diagnostic

Classification Name: Diagnostic intravascular catheter
Class II per 21 CFR §870.1200
Product Code: DQO

Predicate Device:

Device Name	Manufacturer	510(k) clearance #
Radifocus Optitorque Angiographic Catheter	Terumo Medical Corporation	K082736

Device Description: Medtronic’s DxTerity™ Catheters are specialized diagnostic intravascular catheters used for the coronary diagnostic angiography performed as part of diagnostic cardiac catheterization. The basic design of DxTerity™ Catheters comprises of a catheter tube having a proximal end and a distal end. A lumen extends from the proximal end of the DxTerity™ catheter to the distal end of the catheter and is

configured to serve as a conduit for contrast media delivery, catheter flushing and pressure measurement during cardiac catheterization procedure. The lumen of the catheter is also designed to house a guidewire. The DxTerity™ Catheters are designed to allow access into the arterial vasculature from access sites such as femoral, radial and brachial arteries. DxTerity™ Catheters are single-use use devices sold in a sterile condition.

Statement of Intended Use:

The diagnostic catheter is indicated for cardiac and vascular procedures. It is designed to deliver radiopaque media, guidewires, and therapeutic agents to selected sites in the vascular system. The different configurations of the diagnostic catheter are designed to be used in arteries from access sites such as the radial, brachial, and femoral arteries.

Summary of Technological Characteristics:

Medtronic's DxTerity™ Catheters comprises of following technological characteristics:

- Catheter length: 100-125cm
- Catheter size: 5-6 French
- Design Components/ Construction:
 - Hub
 - Strain Relief
 - Lubricous shaft comprising of:
 - Inner liner
 - Braid wire
 - Outer polymeric jacket
 - Soft tip
 - Sleeve

Comparison to the predicate devices:

The following information outlines the differences and similarities between the subject device and the predicate device:

- Similar Intended Use/ Indication for Use
- Similar Device Design Component/ Construction
- Different device materials
- Similar packaging type
- Similar sterilization technology/ method

Medtronic's DxTerity™ Angiography Catheter is substantially equivalent to the predicate device based on similarities in intended use and technological characteristics. The testing performed on the DxTerity™ Catheters demonstrates that the technological differences do not raise any new concerns of safety and effectiveness.

Summary of Non-clinical Data:

The following non-clinical testing was performed to assess safety and effectiveness of Medtronic's DxTerity™ Angiography Catheters:

1. Design Verification Testing/ In-vitro bench testing:

Design Verification (DV) testing was completed to demonstrate that the DxTerity™ Catheters meet the key safety and effectiveness requirements for its intended clinical use. The Design Verification Testing included *in-vitro* bench testing on finished devices which were representative of commercial device. The in-vitro bench tests were performed in accordance with the requirements of the ISO 10555-1: 2013 – *Intravascular catheters—Sterile and single-use catheters—Part 1: General Requirements*

2. Biocompatibility Testing:

The following Biocompatibility Testing was completed on the DxTerity™ Catheters in compliance with the requirements of ISO 10993-1: 2009/ Cor 1: 2010- *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.*

- Cytotoxicity testing
- Sensitization testing
- Intracutaneous reactivity testing
- Acute systemic toxicity testing
- Pyrogenicity testing
- Genotoxicity testing
- Hemolysis testing
- C3a and SC5b-9 Complement Activation study
- Partial Thromboplastin Time study

- *In-vivo* Thromboresistance testing

No new safety or effectiveness issues were raised during the testing. The bench testing qualification and biocompatibility testing demonstrated that Medtronic's DxTerity™ Angiography Catheter is substantially equivalent to the predicate device.

**Summary of
Clinical Data:**

No clinical investigation was performed on the subject device (DxTerity™ Angiography Catheter).

**Conclusion from
Data:**

The data provided in this 510(k) premarket notification demonstrated that the subject device is substantially equivalent to the predicate device.