September 20, 2019

Medtronic Vascular
Colleen Mullins, MSRA, RAC
Principal Regulatory Affairs Specialist
37a Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K192296
Trade/Device Name: Medtronic 6F Taiga Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 22, 2019
Received: August 23, 2019

Dear Colleen 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Lydia Glaw
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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192296

Device Name
Medtronic 6F Taiga Guiding Catheter

Indications for Use *(Describe)*
The Medtronic Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K192296 Special 510(k) Summary

Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923, USA
Contact Person:	Colleen Mullins Principal Regulatory Affairs Specialist 37A Cherry Hill Drive Danvers, MA 01923 USA Phone: (978)-739-3267 Email: colleen.mullins@medtronic.com
Date Prepared:	September 20, 2019
Trade Name:	Medtronic 6F Taiga™ Guiding Catheter
Common Name:	Guiding Catheter
Classification Name:	Percutaneous Catheter Product Code DQY.
Predicate Device:	Medtronic 6F Taiga™ Guiding Catheter - K083422
Device Description:	Medtronic 6F Taiga Guiding Catheter is an intravascular catheter that is supplied sterile and intended for single use only. The primary function of the 6F Taiga Guiding Catheter is to provide a pathway through which therapeutic devices are introduced. Medtronic 6F Taiga Guiding Catheter has a 6F outer diameter (0.082") and is be available in variety of curves and lengths, identical to the predicate Medtronic Taiga Guide Catheter. The various curves and lengths available, will allow the catheter to accommodate the varying patient vascular system anatomies
Statement of Intended Use:	The Medtronic Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.

Summary of Technological Characteristics:

The 6F Taiga Guiding Catheter consists of the following technical characteristics:

- Catheter length: 30-130 cm
- Catheter size: 6 French
- Design Components/ Construction:
  - Luer Hub
  - Strain Relief
  - Shaft comprising of:
    - Inner liner
    - Braid wire
    - Outer jacket
    - Intermediate layer
  - Soft tip
  - Distal Segments
  - Sleeve

Compared to the predicate device, the subject device was modified to include a specification related to the soft tip component.

Summary of Non-clinical Data:

The device performance/ bench tests and biocompatibility tests were conducted in accordance to the relevant FDA guidance to demonstrate substantial equivalence to the legally marketed predicate devices.

Performance/ Bench Testing: The following bench tests were performed on the predicate Taiga Guide Catheters:

1) Shaft Inner Diameter
2) Shaft Outer Diameter
3) Segments Outer Diameter
4) Sleeve Outer Diameter
5) Overlap Segment/Shaft OD
6) Usable Length
7) Soft Tip Exposed Length
8) Shaft Stiffness @ Room Temp
9) Shaft Kink @ Room Temp
10) Shaft Stiffness @ Body Temp
11) Shaft Kink @ Body Temp
12) Shaft Torque
13) Shaft Kink
14) Shaft Torque to separation
15) Shaft Crush
16) Shaft Tensile
17) Primary Stiffness

18) Secondary Stiffness
19) Arch Stiffness @ Room Temp
20) Arch Kink @ Room Temp
21) Arch Stiffness @ Body Temp
22) Arch Kink @ Body Temp
23) Segment Crush
24) Ostial Engagement
25) Secondary Curve Retention
26) Primary Curve Retention
27) Segment Tensile
28) Soft Tip Tensile*
29) Soft Tip Compression*
30) Hub Tensile
31) Pressure and Leak Resistance
32) Inner Lubricity

*These tests, Soft Tip Tensile and Soft Tip Compression, were performed on the subject device to demonstrate substantial equivalence to the predicate Taiga device for the modification in this premarket notification.

Biocompatibility Testing: Pursuant to the ISO 10993-1 *Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process;* the biocompatibility testing for the predicate Taiga Guide Catheter represents the modified Taiga Guide Catheter has met all requirements.

The performance testing along with biocompatibility testing demonstrated that the modified Taiga Guide Catheters are substantially equivalent to the predicate device.

Summary of Clinical Data: No clinical investigation has been performed on the modified device.

Conclusion from Data: Medtronic Vascular has demonstrated that the modified Taiga Guide Catheters are substantially equivalent to the legally marketed predicate devices based on its intended use and technological characteristics.