June 30, 2023

Medtronic Vascular
Shalin Parikh
Senior Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K230156
Trade/Device Name: 5F Launcher Guide Catheter, 6F Launcher Guide Catheter, 7F Launcher Guide Catheter, 8F Launcher Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 2, 2023
Received: June 2, 2023

Dear Shalin Parikh:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.06.30 11:55:45 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230156

Device Name
5F Launcher Guide Catheter
6F Launcher Guide Catheter
7F Launcher Guide Catheter & 8F Launcher Guide Catheter

Indications for Use *(Describe)*
The Medtronic guide catheter is designed to provide a pathway through which therapeutic devices are introduced. The guide 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Medtronic

Medtronic Vascular
37A Cherry Hill Dr
Danvers MA 01923
www.medtronic.com

510(k) Summary (As required by 21 CFR 807.92)

510(k) Number: K230156

510(k) Type: Special 510(k)

Submitter: Medtronic Vascular

37A Cherry Hill Drive,

Danvers, Massachusetts 01923, USA

Contact Person: Name: Shalin Parikh

Designation: Senior Regulatory Affairs Specialist

Email : shalin.a.parikh@medtronic.com

Phone: (978) 739-3047

Date Prepared: June 2, 2023

Trade Name(s):
1. 5F Launcher™ Guide Catheter
2. 6F Launcher™ Guide Catheter
3. 7F Launcher™ Guide Catheter
4. 8F Launcher™ Guide Catheter

Common Name: Percutaneous Guide Catheter

Classification Name: Percutaneous, Catheter

Class II per 21 CFR §870.1250

Product Code: DQY

Predicate Device:

510(k) Number	Device Name	Manufacturer	Product Code
K022764 (2002)	7F Launcher Guide Catheter	Medtronic Vascular	DQY
This predicate has not been subject to a design-related recall.			

Medtronic

Medtronic Vascular
37A Cherry Hill Dr
Danvers MA 01923
www.medtronic.com

Reference Devices:

510(k) Number	Device Name	Manufacturer	Product Code
K132673 (2013)	5F Launcher Guide Catheter	Medtronic Vascular	DQY
K132673 (2013)	6F Launcher Guide Catheter	Medtronic Vascular	DQY
K103386 (2010)	8F Launcher Guide Catheter	Medtronic Vascular	DQY

Device Description:

Launcher Guide Catheters are comprised of a cylindrical catheter having a proximal and distal end. A single lumen extends from the proximal to the distal end of the catheter. The distal end is the section of the catheter towards the tip and the proximal end is towards the hub and strain relief. The guide catheter is comprised of a luer hub, strain relief, shaft, segments, tungsten marker band, sleeve, and soft tip. The catheter shaft is made of three distinct layers. The guide catheter is available in various lengths ranging from 45 cm to 130 cm and four French sizes [5F, 6F, 7F, and 8F]. Launcher Guide Catheters have a lubricious inner lumen that runs from the proximal to the distal end of the catheter via a lubricious liner material or coating on the inner lumen.

Intended Use/Indications for Use:

The Medtronic Guide Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guide catheter is intended to be used in the coronary or peripheral vascular system.

Comparison to the predicate devices:

The subject devices and predicate device are substantially equivalent. The predicate device is Medtronic Vascular's own legally marketed device. The indications for use/intended use of the subject device and predicate device is same. The catheter shaft design of subject devices is identical to that of predicate device. The components of catheter shaft, distal end and proximal end are the same and the devices have same fundamental operating principle. There are no changes to the sterilization method, sterility assurance level, packaging process, packaging materials, packaging configuration and shelf life of the subject devices in comparison to the predicate devices. The differences in catheter's dimensional, performance and materials related technological characteristics identified between the subject (modified) devices and the predicate (previously cleared) device do not raise different questions of safety and effectiveness.

Medtronic

Medtronic Vascular
37A Cherry Hill Dr
Danvers MA 01923
www.medtronic.com

Summary of Non-clinical Data/Performance Testing:

The following tests were performed to evaluate and demonstrate substantial equivalence. The necessary test performed met the acceptance criteria and demonstrated that there are no safety or effectiveness concerns. The following tests were performed:

Biocompatibility Assessment

The biocompatibility evaluation for Launcher Guide Catheter was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1,"Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" dated September 04, 2020. The biological evaluation included the following:

1) Cytotoxicity
2) Sensitization
3) Intracutaneous Reactivity
4) Material-Mediated Pyrogenicity
5) Hemocompatibility
6) Acute Systemic Toxicity

Product Performance Evaluation [Dimensional & Performance]

1) Inner Diameters (shaft, tip, & hub*)
2) Outer Diameters (shaft, segment, soft tip sleeve, & segment/shaft overlap)
3) Total Segment Length
4) Effective Length*
5) Exposed Tip Length
6) Luer Connector Performance*
7) Leak Resistance*
8) Draw-through stiffness of primary and secondary curve
9) Shaft bending stiffness & bending kink resistance (Body temperature and room temperature)
10) Arch bending stiffness & bending kink resistance (Body temperature and room temperature)
11) Shaft & distal segment crush resistance
12) Torsional Stiffness, Rotational Kink Angle, and Rotations to Separation
13) Curve retention after simulated seating
14) Peak shaft & segment tensile load

Medtronic

Medtronic Vascular
37A Cherry Hill Dr
Danvers MA 01923
www.medtronic.com

15) Peak soft tip tensile load
16) Soft tip stiffness
17) Peak hub/shaft tensile load*
18) Internal lubricity

*These tests were performed on the subject device to demonstrate substantial equivalence to the predicate device for the modifications in this premarket notification. Relevant standards for these tests detailed below.

Luer Connector Performance testing conducted in accordance with the following standards:

- ISO 594-1 First edition 1986-06-15 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements
- ISO 594-2 Second edition 1998-09-01 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- EN ISO 80369-7 Second edition 2021-05 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

Leak Resistance and Peak Hub/Shaft Tensile Load testing conducted in accordance with the following standard:

- ISO 10555-1 Second Edition 2013+A1:2017 Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements – Amendment 1

The performance testing along with biocompatibility testing demonstrated that the subject device Launcher Guide Catheter is substantially equivalent to the predicate device.

Summary of Clinical Data: No clinical testing data was required for this special 510k submission.

Conclusion from Testing Data: The differences between subject devices and predicate devices have been evaluated through non-clinical testing. Based on the results of the testing performed, the subject devices are demonstrated as substantially equivalent to the predicate device.