March 22, 2019

Medtronic Inc.
Elaine Gullane
Principal Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K183353
Trade/Device Name: Telescope™ Guide Extension Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 20, 2019
Received: February 22, 2019

Dear Elaine Gullane:

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

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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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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: 2019.03.22 12:09:56 -04'00'

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

Enclosure

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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)*

K183353

Device Name

Telescope™ Guide Extension Catheter

Indications for Use *(Describe)*

Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

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 per 21 CRF 807.92

Date Prepared:	30th November 2018
Applicant:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Official Correspondent:	Elaine Gullane Principal Regulatory Affairs Specialist Medtronic Ireland Parkmore Business Park West Galway Ireland Phone: (353) 91 708682 Fax: (353) 91 708672 Email: elaine.gullane@medtronic.com
Proprietary Name:	Telescope™ Guide Extension Catheter
Common Name:	Guide Catheter
Device Classification:	Class II
Regulation Number:	21 CFR 870.1250
Classification Name:	Percutaneous catheter
Product Code:	DQY

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Device Description:

The Telescope guide extension catheter is a single-lumen rapid exchange catheter. The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.

The Telescope™ Guide Extension Catheter is offered in sizes compatible with 6F and 7F guide catheters as indicated by the product model numbers below.

Size	Product Model Number
6F	TELE6F
7F	TELE7F

Indications For Use:

Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

Substantially Equivalent Device:

GuideLiner V3 Catheter (K172090, cleared October 20, 2017).

Summary of Technological Differences to the Predicate Device:

The following outlines the differences and similarities between the subject device - Telescope™ Guide Extension Catheter and the predicate device - GuideLiner V3 Catheter:

- Similar Intended Use
- Similar Device Design Component/Construction
- Different device materials
- Similar Packaging
- Similar Sterilization Method

Medtronic's Telescope™ Guide Extension Catheter is substantially equivalent to the predicate device based on similarities in intended use and technological characteristics. The testing performed demonstrates that the technological differences in the new device do not raise new questions of safety and effectiveness.

Summary of Non-Clinical Data:

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and design verification tests to provide evidence of substantial equivalence for the Telescope™ Guide Extension Catheter. The Telescope™ Guide Extension Catheter is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following:

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