November 26, 2018

Medtronic CryoCath LP
Natalie Sadeghi
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
MVS 46
Mounds View, Minnesota 55112

Re: K183174
Trade/Device Name: FlexCath Advance Steerable Sheath and Dilator
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: November 15, 2018
Received: November 16, 2018

Dear Natalie Sadeghi:

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/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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183174

Device Name
FlexCath Advance ™ Steerable Sheath and Dilator

Indications for Use *(Describe)*
The FlexCath Advance Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The Sheath deflection facilitates catheter positioning.

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.

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Department of Health and Human Services
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Office of Chief Information Officer
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"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."

5.0 510(k) Summary

Date Summary Prepared:	November 12, 2018
Applicant:	Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec H9R 5Z8, Canada **Establishment Registration No. 3002648230**
Official Correspondent:	Natalie Sadeghi Principal Regulatory Affairs Specialist Medtronic CryoCath LP 8200 Coral Sea Street Mounds View, MN 55112 Telephone: 763.526.1035 Fax: 763.367.9903 Email: natalie.t.sadeghi@medtronic.com
Device Trade Name:	FlexCath Advance™ Steerable Sheath and Dilator
Common Name:	Steerable Sheath and Dilator
Classification Name:	Steerable Catheter
Classification & Panel:	Class II, 21 CFR 870.1280, Cardiovascular
Product Code:	DRA
Predicate Device:	FlexCath Advance™ Steerable Sheath and Dilator (K123591)
Device Description:	The FlexCath Advance Steerable Sheath is a sterile, single use percutaneous introducer fitted with a valve to allow for introduction, withdrawal and swapping of catheters and wires while minimizing blood loss. A side-port with stopcock is integrated to allow continuous drip infusion, injection through the center lumen, flushing, aspiration, blood sampling and pressure monitoring. The FlexCath can be deflected to provide additional maneuverability to catheters that are advanced through the sheath and into the right or left chamber of the heart. The FlexCath Advance Steerable Sheath is comprised of two (2)

510(k) Summary of Safety and Effectiveness

main sections: the shaft and the handle. A dilator is included with each sheath.

This premarket notification presents proposed updates to the Instructions for Use (IFU) manual; changes resulting in the subject device are limited to these IFU updates only. All other aspects of the device (design/technology, performance specifications, etc.) remain unchanged and are identical as compared to the predicate device, the FlexCath Advance originally cleared under K123591.

Intended Use:

Facilitates introducing various cardiovascular catheters into the heart.

The intended use is unchanged with the proposed IFU update and remains the same as previously cleared under K123591.

Indications for Use:

The FlexCath Advance Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.

The indications for use is unchanged with the proposed IFU update and remains the same as previously cleared under K123591.

Comparison of Technological Characteristics:

There are no changes to the predicate device specifications or technological characteristics associated with the proposed IFU update. Compared to the predicate, the subject device features the:

- Same intended use
- Same indications for use
- Same fundamental scientific technology
- Same unidirectional deflection
- Same sheath and dilator design
- Same user interface
- Same materials of construction
- Same sterilization process
- Same packaging configuration and labels

The differences between the subject device and the predicate device are limited to the IFU content only. The updates to the US IFU were proposed to align with recent updates for the FlexCath Advance Japan package insert to ensure consistency

510(k) Summary of Safety and Effectiveness

	across the global labeling. The subject device design technology, performance characteristics, materials, shelf life and sterilization process are all unchanged with this IFU update. The proposed IFU updates do not constitute a change in the fundamental scientific technology for the proposed device and do not raise new or different questions of safety and effectiveness. The subject device does not provide a new therapy, and the intended use and indications for use remain unchanged and identical to the predicate. The FlexCath Advance featuring the updated IFU as described in this 510(k) submission is substantially equivalent to the predicate device.
Performance Data:	No performance testing (bench, animal or clinical) was required to support the proposed IFU updates. The existing performance data previously submitted under K123591 remains valid and applicable for this subject device.
Conclusion:	This premarket notification is limited to updates to the FlexCath Advance Instructions for Use manual, to align the global labeling for the FlexCath Advance sheath. There are no changes to the device specifications or technological characteristics. The IFU update for the subject device does not raise any new questions of safety or effectiveness as compared to the device as previously cleared under K123591.