November 13, 2020

Medtronic CryoCath LP
Matthew Lobeck
Pr. Regulatory Affairs Specialist
8200 Coral Sea Street NE, MVS 46
Mounds View, Minnesota 55112

Re: K202620
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: September 9, 2020
Received: September 10, 2020

Dear Matthew Lobeck:

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,

Mark Fellman
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
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)*
K202620

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.

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5.0 510(k) Summary

Date Summary Prepared: September 9th, 2020

Applicant:
Medtronic CryoCath LP
9000 Autoroute Transcanadienne
Point-Claire, Quebec
H9R 5Z8, Canada
Establishment Registration No. 3002648230

Official Correspondent:
Matthew Lobeck
Principal Regulatory Affairs Specialist
Medtronic
8200 Coral Sea Street
Mounds View, MN 55112
Work: 763.514.9515
Mobile: 612-202-5925
Fax: 763.367.9903
Email: matthew.lobeck@medtronic.com

Device Trade Name: FlexCath Advance Steerable Sheath and Dilator

Common Name: Steerable Sheath and Dilator

Classification Name: Catheter, Steerable

Classification & Panel: Class II, 21 CFR 870.1280, Cardiovascular

Product Code: DRA

Predicate Device: FlexCath Advance Steerable Sheath and Dilator - K183174

Device Description: The FlexCath Advance Steerable Sheath and Dilator 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 Advance Steerable Sheath and Dilator 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 sheath is comprised of two (2) main sections: the shaft and the handle. A dilator is included

	with each sheath. This premarket notification presents proposed design and material changes to the hemostasis valve component, located within the handle section. Product performance requirement changes related to the updated hemostasis valve are also being implemented for the subject device. All other aspects of the device (overall design/technology, labeling, etc.) remain unchanged and are identical as compared to the predicate device, the FlexCath Advance Steerable Sheath and Dilator cleared under K183174.
Intended Use:	Facilitates introducing various cardiovascular catheters into the heart. The intended use is unchanged with the proposed modifications and remains the same as that previously cleared under K183174.
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 are unchanged with the proposed modifications and remains the same as that previously cleared under K183174.
Comparison of Technological Characteristics:	The modified FlexCath Advance Steerable Sheath and Dilator features the following similarities with the predicate device: • Same intended use • Same indications for use • Same product labeling • Same fundamental scientific technology • Same unidirectional deflection • Same shaft and dilator design and materials • Same user interface • Same sterilization processes • Same packaging configuration The differences between the modified FlexCath Advance Steerable Sheath and Dilator and predicate devices involve the following:

- Dimensional changes to the design of the hemostasis valve component
- Material change to the hemostasis valve component
- Addition of silicone oil to the hemostasis valve.
- Updates to product performance requirements related to the modified hemostasis valve

The proposed changes do not constitute a change in the fundamental scientific technology for the subject 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 modified subject device described in this 510(k) submission is substantially equivalent to the predicate device.

Performance Data:

Performance testing (bench) was completed in support of the proposed modifications. The results of the design verification testing completed in support of the proposed changes demonstrate that the modified FlexCath Advance Steerable Sheath and Dilator in scope of this premarket notification meets all applicable product requirements.

The following design verification tests were successfully completed in support of the modified FlexCath Advance (subject device). All acceptance criteria were met, demonstrating compliance with the applicable product requirements:

- Pressure decay and vacuum testing
- Kink testing
- Pull force testing
- Insertion and retraction force testing

All design verification testing was performed on final finished product incorporating the proposed design and material changes.

Biocompatibility of the subject device was assessed via the following testing, in accordance with ISO 10993-1:2018:

- Cytotoxicity testing
- Sensitization testing
- Irritation or Intracutaneous Reactivity testing
- Systemic Toxicity testing (acute)

- Pyrogenicity testing (Material-mediated)
- Hemocompatibility (Hemolysis, Complement Activation)
    - The following additional hemocompatibility testing and safe history of use was leveraged from the predicate device:
        - Thrombogenicity in vivo
        - Coagulation, PTT test
        - Platelets
        - Hematology

The results of the biocompatibility testing completed and leveraged support the conclusion that the subject device is biologically safe as guided by ISO 10993-1:2018 for use in its intended application.

A sterilization qualification study was conducted for adoption of the modified FlexCath Advance (subject device) into the existing, validated EO sterilization cycle. The following tests were performed:

- EO Residual testing
- Bioburden testing
- Bacterial endotoxin testing

Qualification testing results for EO residuals, bioburden, and bacterial endotoxin met their respective acceptance criteria with valid assays conducted by qualified laboratories.

Conclusion:

There are no changes to the intended use, indications for use, or fundamental scientific technology between the subject and predicate devices. Design verification testing was completed to verify that the performance of the modified FlexCath Advance Steerable Sheath and Dilator. All results demonstrate the properties and performance of the modified FlexCath Advance Steerable Sheath and Dilator are suitable for the intended use. There are no differences between devices identified in testing that raised new questions of safety or effectiveness, and the subject device is considered substantially equivalent to the legally marketed predicate device.