DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 2, 2017

Medtronic CryoCath LP
Natalie Sadeghi
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE, Mail Stop MVS46
Mounds View, Minnesota 55112

Re: K163268
Trade/Device Name: FlexCath™ Select Steerable Sheath and Dilator
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 18, 2016
Received: November 21, 2016

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. 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.

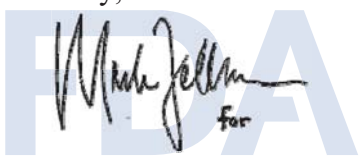
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163268

Device Name
FlexCath™ Select Steerable Sheath and Dilator

Indications for Use *(Describe)*
The FlexCath Select Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum. 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)

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510(k) Summary of Safety and Effectiveness

Date Summary Prepared: November 16, 2016

Applicant:

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Establishment Registration No. 3002648230

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Device Trade Name: FlexCath™ Select Steerable Sheath and Dilator

Common Name: Steerable Sheath and Dilator

Classification Name: Introducer, Catheter

Classification & Panel: Class II, 21 CFR 870.1340, Cardiovascular

Product Code: DYB

Predicate Device: FlexCath® Select™ Steerable Sheath & Dilator (K142684)

Device Description: The Medtronic FlexCath™ Select Steerable Sheath is a sterile, single-use, percutaneous catheter introducer fitted with a valve to allow for introduction, withdrawal, and exchange 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. A dilator is packaged with the FlexCath Select.

The handle incorporates a deflection mechanism and a deflection wire that is integrated into the catheter shaft. This allows the sheath to be deflected to provide additional maneuverability to catheters that are advanced through the

510(k) Summary of Safety and Effectiveness

sheath into the right or left chamber of the heart. The FlexCath Select sheath is comprised of two (2) main sections: the shaft and the handle.

Intended Use:

Facilitates introducing various cardiovascular catheters into the heart.

This is the same intended use as previously cleared for the original FlexCath Select Steerable Sheath and Dilator, predicate device (K142684).

Indications for Use:

The FlexCath Select Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum. The sheath deflection facilitates catheter positioning.

The indications for use are the same as previously cleared for the original FlexCath Select Steerable Sheath and Dilator, predicate device (K142684).

Comparison of Technological Characteristics :

The FlexCath Select Steerable Sheath and Dilator has the following similarities to the predicate device:

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

The differences between the modified FlexCath Select and the predicate device consist of the following:

- Minor dimensional changes to hemostasis valve assembly components
- Modified molding process temperature for the valve seal component
- Added silicone oil to the entire length of the dilator component; this silicone oil was present on the predicate device hemostasis valve

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These changes do not constitute a change in the fundamental scientific technology for the proposed device; the differences between the modified FlexCath Select and the predicate do not raise new or different questions of safety and effectiveness. The FlexCath Select does not provide a new therapy, and the intended use and indications for use remain equivalent to that of the predicate. The modified FlexCath Select described in this Traditional 510(k) submission is substantially equivalent to the predicate device, reference **Table 1**.

Table 1. Substantial Equivalence for FlexCath Select

Characteristic	PREDICATE DEVICE: FlexCath Select Steerable Sheath (Model 990065) K142684	SUBJECT DEVICE: FlexCath Select Steerable Sheath (Model 990065)
Intended Use		
Intended Use	Facilitates introducing various cardiovascular catheters into the heart.	Same
Indications for Use	The FlexCath Select Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum. The sheath deflection facilitates catheter positioning.	Same

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Contraindications	The FlexCath Select Steerable Sheath is contraindicated for placement in the left atrium or ventricle if any of the following conditions apply to the patient: • The patient has an intra-atrial septal patch or occluder, or has had other surgical intervention in or adjacent to the intra-atrial septum. • The patient has a left atrial thrombus. The patient has known or suspected atrial myxoma.	Same
Technology		
Steerable catheter introducer	Yes	Same
Design		
Unidirectional	Yes	Same
Hemostasis valve	Yes	Same
Deflectable	Yes	Same
Side flush port tubing	Yes	Same
Stopcock at the end of side port tubing	Yes	Same
Handle	Yes	Same
Braided Shaft	Yes	Same
Sheath OD (inches/ French)	0.170" (13F)	Same
Sheath ID (inches/ French)	0.131" (10F)	Same
Total length (cm)	81 cm	Same
Usable length (cm)	65 cm	Same

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Distal Flush Holes (quantity)	3	Same
Deflection	≥ 135°, when loaded with the Freezor MAX CryoAblation Catheters – Models 239F3. 239F5 (*P010010*), or a phased RF PVAC Model 990078 (*G120067*).	Same
Deflection Reach length	5.5cm	Same
Guidewire	Not included in package	Same
Valve seal volume	0.645cm^3	0.584cm^3
Valve cap ID	0.171″	0.140″
Valve hub distal ID	0.412″	0.420″
Strain Relief ID	0.165″	Same
Dilator OD	0.128″	Same
Dilator ID	0.038″	Same
Dilator usable length (cm)	82.88 cm (32.63″)	Same
Dilator total length (cm)	85.74 cm (33.755″)	Same
Dilator shape	Pre-curved 55° tip	Same
Dilator color	Hub – White Shaft – White	Same
Materials		
Sheath shaft	Pebax with 20% Barium Sulfate, stainless steel braid and PTFE liner	Same
Adhesive (shaft to hub -sheath valve assembly)	Loctite 4310	Same
Hemostasis valve material (seal)	Medalist MD200, Nusil MED-400 silicone fluid	Same
Hemostasis hub and cap material	Hub: Calibre 2081-15 FC030004 (Poly Carbonate) Cap: PRO-FAX 6523 (Polypropylene)	Same

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Hemostasis valve (stopcock)	Body: MAKROLON RX 1805 451118 (Polycarbonate) Handle:HDPE HD6706.17 Extension Tube: Polyurethane (Pellethane 2363-80A)	Same
Dilator shaft and hub material	Copolyester TPE (Hytrel 7246 with 40% BaSO4)	Copolyester TPE (Hytrel 7246 with 40% BaSO4) **Coating: NuSil MED-400 Silicone oil fluid**
Pouch material	Tyvek/nylon polyethylene pouch	Same
Sterility, Shelf Life		
Sterilization Method	Ethylene Oxide (EtO)	Same
Usage	Single use and disposable	Same
Shelf Life	2 years	Same

Performance Data: Bench testing was completed to support the proposed modifications to the FlexCath Select. Performance testing verified that the subject device performs as designed and is suitable for the intended use.

Testing included:

- Leak/air ingress performance – Hemostasis valve
- Valve performance following insertion/removal cycling – sheath/valve
- Dilator insertion/removal force
- Bond pull force – sheath/hub
- Compatibility verification

Conclusion: Design verification testing was performed to verify that the performance of the modified FlexCath Select remains substantially equivalent to the predicate device. All results demonstrate that the properties and performance of the modified FlexCath Select are suitable for the intended use. There are no differences between devices identified in testing that raised new questions of safety or effectiveness.