DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2015

Medtronic Cryocath Lp
% Vanessa Ware
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mail Stop Mvs46
Mounds View, Minnesota 55112

Re: K142684
Trade/Device Name: FlexCath Select Steerable Sheath and Dilator (Model 990065)
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA, DYB
Dated: November 6, 2014
Received: November 6, 2014

Dear Vanessa Ware:

This letter corrects our substantially equivalent letter of November 6, 2014.

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.

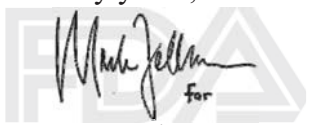
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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" (21CFR 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 yours,



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)*
K142684

Device Name
FlexCath Select ™ Steerable Sheath and Dilator (Model 990065)

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)

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."

5.0 510(k) K142684 Summary of Safety and Effectiveness

5.1 General Information:

Date Summary Prepared:	September 17, 2014
Applicant:	Medtronic CryoCath LP 9000 Autoroute Transcanadienne Pointe-Claire, Quebec H9H 5Z8, CANADA **Establishment Registration No. 3002648230**
Contact Person:	Vanessa Ware Principal Regulatory Affairs Specialist Medtronic CryoCath LP Coral Sea Street Mounds View, MN 55112 Telephone: 763.526.2743 Fax: 763.367.9903 Email: vanessa.d.ware@medtronic.com
Trade Name:	FlexCath® Select™ Steerable Sheath & Dilator Steerable Catheter
Common Name:	Steerable Sheath and Dilator
Classification Name:	Steerable Catheter
Classification & Panel:	Class II, 21 CFR § 870.1280, Cardiovascular
Product Code:	DRA, DYB
Predicate Device(s):	FlexCath® Advance™ Steerable Sheath & Dilator, Model 4FC12 (K123591) HeartSpan® Steerable Introducer, Models FST-085-00 FST-085-01 and FST-085-02 (K132164).

5.2 Device Description

The FlexCath Select 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 preventing air ingress and 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 Select Steerable Sheath can be deflected to provide additional maneuverability to catheters that are advance through the sheath and into the right or left chamber of the heart. The FlexCath Select Steerable Sheath is comprised of two (2) main sections: the shaft and the handle. A dilator is included with each sheath.

This application introduces FlexCath Select 10 French (10Fr) FlexCath Select Steerable Sheath (990065), which is a modification of the 12 French (12Fr) FlexCath Advance Sheath (4FC12). Modifications were made to the shaft, cap and strain relief components, hemostasis valve assembly (stopcock, valve, and hub), dilator, new adhesive material and packaging tray cavity. In addition, the Indicates for Use were expanded to include introduction into the left side of the heart through the interatrial septum (transseptal puncture). Finally the Technical Manual (Instructions for Use) and updated packaging labeling was developed for the FlexCath Select Steerable Sheath.

5.3 Intended Use

Facilitates introducing various cardiovascular catheters into the heart.

5.4 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 FlexCath Select Steerable Sheath and Dilator's Indications for Use is substantially equivalent to the predicate HeartSpan Steerable Introducer. In addition, the HeartSpan Steerable Introducer has an acceptable clinical performance as there are no recalls or safety alerts associated with this device.

The primary predicate, FlexCath Advance, is contraindicated for transseptal puncture because it does not support the use of the transseptal needle or transseptal puncture as it is not resistant to skiving and damage from use with a transseptal needle. The material used on the proposed dilator is stiffer compared to the dilator material on the primary predicate FlexCath Advance. The materials are identical to the predicate HeartSpan Steerable Introducer which was chosen because it is resistant to skiving and damage from use with a transseptal needle.

The modified dilator (which can be used for transseptal puncture) introduces several new failure modes that the primary predicate FlexCath Advance did not have related to the compatibility with transseptal needles and the septal wall crossing/puncture. These risks have been classified as a risk level of 2 (Medium Risk/As Reasonably Practical) based on the predicate HeartSpan dilator and our internal testing, and are all inherent to a transseptal procedure. When procedures are on the left side of the heart, the FlexCath Select Steerable Sheath and Dilator allows for the use of only one sheath (with the dilator) to perform both the transseptal puncture and catheter manipulation versus exchanging a sheath for the transseptal puncture and a different sheath for catheter manipulation. This is an improvement to both operators and patients and is aligned with common practices of other sheaths on the market with transseptal indication.

These residual risks associated with the use of the FlexCath Select Steerable Sheath and Dilator was deemed acceptable. Air embolism was added as a potential adverse event because it is an inherent risk associated with a transseptal puncture leading to the left side of the heart. Refer to **Section 21.0 Risk Management.**

5.4.1 Comparison to the Predicate Device

The FlexCath Select Steerable Sheath and Dilator is substantially equivalent to the predicates outlined in the following comparison tables: **Table 5.1: Substantial Equivalence and Comparison Primary Predicate FlexCath Advance and Table 5.2: Substantial Equivalence and Comparison – Transseptal Indication.**

Table 5.1: Substantial Equivalence and Comparison Primary Predicate FlexCath Advance

Characteristic	PRIMARY PREDICATE: FlexCath Advance Steerable Sheath (4FC12) K123591	MODIFIED DEVICE: FlexCath Select Steerable Sheath (990065)
Instructions for Use		
Intended Use	Facilitates introducing various cardiovascular catheters into the heart.	Same
Indications for Use	The FlexCath 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 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.
Contraindications	The FlexCath Advance Steerable Sheath is contraindicated for placement in the left atrium or ventricle if: • The patient has an intra-atrial septal patch or has had other surgical intervention in or adjacent to the intra-atrial septum. • The patient has had a previous embolic event from the left side of the heart within two months of the procedure. • The patient has known or suspected atrial myxoma. FlexCath should not be used to perform the transseptal puncture.	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.
Performance/Technology		
Steerable catheter introducer	Yes	Same
Design		

Characteristic	PRIMARY PREDICATE: FlexCath Advance Steerable Sheath (4FC12) K123591	MODIFIED DEVICE: FlexCath Select Steerable Sheath (990065)
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	New Stopcock design in which the side port tubing is inserted inside the stopcock
Handle	Yes	Same
Braided Shaft	Yes	Same
Sheath OD (inches/ French)	0.198" (15F)	0.170" (13F)
Sheath ID (inches/ French)	0.158" (12F)	0.131" (10F)
Total length (cm)	86.4 cm	Same
Usable length (cm)	65cm	Same
Distal Flush Holes (quantity)	3	Same
Deflection	≥ 135°, when loaded with an Arctic Front or Arctic Front Advance balloon catheter (PMA P010010)	≥ 135°, when loaded with the Freezor MAX CryoAblation Catheters – Models 239F3. 239F5 (P010010), and a phased RF PVAC Model 990078 (G120067).
Deflection Reach length	5.5cm	Same
Guide wire	Not included in the package	Same
Cap ID	0.204"	0.178"
Strain Relief ID	0.190"	0.165"
Dilator OD	0.154"	0.128"
Dilator ID	0.039"	0.038"
Dilator usable length (cm)	83.5 cm	82.88 cm
Dilator total length (cm)	87 cm	85.74 cm
Dilator shape	Straight	Pre-curved 55 degree tip
Dilator color	Hub – White Shaft – Blue (Pantone 278C)	Hub – White Shaft – White
	Materials	
Shaft Material	Pebax with 20% Barium Sulfate, stainless steel braid and PTFE liner	Same
Adhesive (shaft to hub - sheath valve assembly)	Loctite 416	Loctite 4310
Hemostasis valve material	Molded silicone rubber	Medalist MD200 (Thermoplastic Elastomer)

Characteristic	PRIMARY PREDICATE: FlexCath Advance Steerable Sheath (4FC12) K123591	MODIFIED DEVICE: FlexCath Select Steerable Sheath (990065)
Hemostasis hub and cap material	Polycarbonate	Hub: Calibre 2081-15 FC030004(Polycarbonate) Cap: PRO-FAX 6523 (Polypropylene)
Hemostasis valve (stopcock)	Polycarbonate	Body: MAKROLON RX 1805 451118 (Polycarbonate) Handle: HDPE HD6706.17
Dilator shaft and hub material	Polyethylene	Copolyester TPE (Hytrel 7246 with 40% BaSO4) Color: White
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	1 year

Table 5.2: Substantial Equivalence and Comparison – Transseptal Indication

Characteristic	PREDICATE: HeartSpan Steerable Introducer (Models FST-085-00, FST-085-01, and FST-085-02) K132164	MODIFIED DEVICE: FlexCath Select Steerable Sheath (Model 990065)
Instructions for Use		
Intended Use	Facilitates introducing various cardiovascular catheters into the heart.	Same
Indications for Use	The HeartSpan Steerable Introducer Kit is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	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.
Contraindications	• Previous intra-atrial septal patch. • Known or suspected atrial myxoma. • Myocardial Infarctions within the last two weeks. • Unstable angina. • Recent Cerebral Vascular Accident (CVA). • Patients who do not tolerate anticoagulation therapy. • Patients with an active infection. • Presence of atrial thrombus.	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 or the intra-atrial septum. • The patient has a left atrial thrombus • The patient has known or suspected atrial myxoma.
Technology/Performance - Dilator		
Steerable catheter introducer	Yes	Same
Design		
Deflectable	Yes	Yes
Dilator OD	0.112” (8.5 F)	0.128” (10 F)
Dilator ID	0.057”	0.038”
Dilator usable length (cm)	94.56 cm (37.23”)	82.88 cm (32.63”)
Dilator total length (cm)	96.19 cm (37.87”)	85.74 cm (33.755”)
Dilator to Guide Wire Compatibility	up to 0.038”	0.032” to 0.035
Materials		

Characteristic	PREDICATE: HeartSpan Steerable Introducer (Models FST-085-00, FST-085-01, and FST-085-02) K132164	MODIFIED DEVICE: FlexCath Select Steerable Sheath (Model 990065)
Dilator shaft and hub material	7246 Hytrel, with 40% Barium Sulfate, Color: White	Same
Sterility, Shelf Life		
Sterilization Method	Ethylene Oxide (EtO)	Same
Usage	Single use and disposable	Same
Shelf Life	3 years	1 year

5.4.2 Technological Characteristics Comparison of Modified Device to Predicate Device

The FlexCath Select Steerable Sheath and Dilator, with the modified hemostasis valve assembly (stopcock, valve, hub) and new adhesive (both transparent to the user), modified dilator (increased stiffness for transseptal puncture), modified shaft, cap and strain relief components and packaging tray cavity has the following similarities to the primary predicate device previously cleared under K123591:

- Same Intended Use
- Same fundamental scientific technology
- Same unidirectional deflection
- Same basic sheath design (dimensions, bullnose tip shape)
- Same user interface with handle (rotating actuator for deflection)
- Same materials
- Same sterilization process

The modified FlexCath Select Steerable Sheath and Dilator has the following similarities to the predicate device previously cleared under K132164.

- Same Intended Use
- Same fundamental scientific technology
- Same materials

5.5 Summary of Performance Data

In-vitro testing was performed to demonstrate substantial equivalence with the predicate devices and also to comply with user needs and safety and effectiveness requirements.

Non-clinical performance testing (bench testing) was performed to support substantial equivalence between the FlexCath Select Steerable Sheath (990065) and the predicate FlexCath Steerable Sheath and Dilator (Model 4FC12) previously cleared under K123591 and HeartSpan Steerable Introducer, (Models FST-085-00, FST-085-01, FST-085-02) previously cleared under

K132164. All relevant key performance attributes were tested on the FlexCath Select against performance requirements, and some tests were leveraged from the predicate device and not repeated.

The FlexCath Select does not provide a new therapy and the intended use remains equivalent to that of approved predicates. However, the indications for use were expanded to include introduction into the left side of the heart through the interatrial septum (transseptal puncture) and are equivalent to that of the approved HeartSpan Steerable Introducer with known acceptable performance which is a market released and commercially available device (Models FST-085-00, FST-085-01, FST-085-02) K132164.

Testing supplied in the 510(k) Notification (**Section 18**) includes formal data collection, mechanical and performance verification, reliability verification, system verification, labeling and Instructions for Use (IFU) verification and validation tests.

It was determined that modifications of features to the FlexCath Steerable Sheath and Dilator had no impact on safety and performance and all testing demonstrated that acceptance criteria were met. In addition, all testing passed by meeting the established requirements for the use of the FlexCath Select Steerable Sheath and Dilator, and the testing demonstrates that the device does not raise new questions of safety or effectiveness when compared to the predicate.

5.6 Conclusion

Design verification testing was performed to verify that the performance of FlexCath Select and Dilator remains substantially equivalent to the predicate devices. All test results demonstrate that the properties and performance of the device are suitable for its intended use. There are no differences between devices or in testing which would raise new issues of safety or effectiveness.