March 22, 2023

Boston Scientific Corporation
Derek Charchuk
Senior Regulatory Affairs Specialist
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798

Re: K223824
Trade/Device Name: POLARSHEATH™ Steerable Sheath 12F, POLARMAP™ Circular Mapping Catheter, POLARMAP™ EP Electrical Cable, SMARTFREEZE™ Esophageal Temperature Sensor (ETS) Cables (SMARTFREEZE™ ETS Cable, SMARTFREEZE™ 16 PIN ETS Cable, SMARTFREEZE™ CIRCA ETS Cable), SMARTFREEZE™ Pressure Sensor Cable
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA, DRF
Dated: December 20, 2022
Received: December 21, 2022

Dear Derek Charchuk:

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 and Part 809); 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,

Aneesh S. Deoras -S

Aneesh Deoras
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223824

Device Name
POLARSHEATH™ Steerable Sheath 12F, POLARMAP™ Circular Mapping Catheter, POLARMAP™ EP Electrical Cable, SMARTFREEZE™ Esophageal Temperature Sensor (ETS) Cables (SMARTFREEZE™ ETS Cable, SMARTFREEZE™ 16 PIN ETS Cable, SMARTFREEZE™ CIRCA ETS Cable), SMARTFREEZE™ Pressure Sensor Cable

Indications for Use *(Describe)*

POLARSHEATH Steerable Sheath 12F:
The POLARSHEATH steerable sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart.

POLARMAP Circular Mapping Catheter:
The POLARMAP Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

POLARMAP EP Electrical Cable:
The EP Electrical Cable is designed for use with the POLARMAP Mapping Catheter and the hospital EP recording system. The EP Electrical Cable connects the POLARMAP Mapping Catheter to the hospital EP recording system. Use of the EP Electrical Cable is optional.

SMARTFREEZE ETS Cables:
The Esophageal Temperature Sensor (ETS) Cable (model M004CRBS6310 or M004CRBS6320) is designed for use with the SMARTFREEZE Console and a general purpose series 400 temperature sensor. The ETS Cable is used to connect a general purpose series 400 temperature sensor to the ICB. Use of the ETS Cable is optional.

The ETS Cable (CIRCA) (model M004CRBS6340) is designed for use with the SMARTFREEZE Console and the CIRCA S-CATH™ Esophageal Temperature Probe. The ETS Cable (CIRCA) is used to connect the CIRCA S-CATH™ Esophageal Temperature Probe to the ICB (Model M004CRBS4130 only). Use of the ETS Cable (CIRCA) is optional.

NOTE: The role of esophageal temperature monitoring using this device in reducing the risk of cardiac cryoablation-related esophageal injury has not been established. The performance of the SMARTFREEZE ETS Cables and compatible temperature probe in detecting esophageal temperature changes as a result of energy delivery during cardiac cryoablation procedures has not been evaluated.

SMARTFREEZE Pressure Sensor Cable:
The Pressure Sensor Cable is designed for use with the SMARTFREEZE Console and the cryoablation balloon catheter. The Pressure Sensor Cable is used to connect an intravascular pressure transducer to the ICB to measure the ventricular pressure during ablation procedures to aid in determining vein occlusion. Use of the Pressure Sensor Cable is optional.

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

510(k) Summary in Compliance with 21 CFR 807.92

I. SUBMITTER INFORMATION

Submitter Name: Boston Scientific Corporation

Submitter Address: 4100 Hamline Avenue North
St. Paul, Minnesota
USA 55112-5798

Contact #1: Derek Charchuk
Senior Regulatory Affairs Specialist
Phone: (905) 696-1913
Email: derek.charchuk@bsci.com

Contact #2: Jim Johnson
Senior Regulatory Affairs Specialist
Phone: (651) 582-5561
Email: jim.johnson@bsci.com

Date Prepared: 19-December-2022

II. DEVICE INFORMATION

Generic Name: Sheath, Mapping Catheter, EP Electrical Cable, Temperature Sensor Cable, Pressure Sensor Cable

Trade Name: POLARSHEATH™ Steerable Sheath 12F
POLARMAP™ Circular Mapping Catheter
POLARMAP™ EP Electrical Cable
SMARTFREEZE™ Esophageal Temperature Sensor (ETS) Cables:

- SMARTFREEZE™ ETS Cable
- SMARTFREEZE™ 16 PIN ETS Cable
- SMARTFREEZE™ CIRCA ETS Cable

SMARTFREEZE™ Pressure Sensor Cable

Product Codes:

DRA: POLARSHEATH™ Steerable Sheath 12F

DRF: POLARMAP™ Circular Mapping Catheter
POLARMAP™ EP Electrical Cable
SMARTFREEZE™ Esophageal ETS Cables

SMARTFREEZE™ Pressure Sensor Cable

Device Class: Class II

Review Panel: Cardiovascular (DRA & DRF)

Classification Regulations:

(21 CFR 870.1280): POLARSHEATH™ Steerable Sheath 12F

(21 CFR 870.1220): POLARMAP™ Circular Mapping Catheter
POLARMAP™ EP Electrical Cable
SMARTFREEZE™ ETS Cables
SMARTFREEZE™ Pressure Sensor Cable

III. PREDICATE DEVICE INFORMATION

Predicate Device #1: Flexcath Advance Steerable Sheath (12 French)

Manufacturer: Medtronic Cryocath LP
510(k) #: K123591
FDA Clearance Date: 27 December 2012
Product Code: DRA
Predicate Device for: POLARSHEATH™ Steerable Sheath 12F

Predicate Device #2: Achieve Advance Mapping Catheter

Manufacturer: Medtronic Inc.
510(k) #: K162892
FDA Clearance Date: 15 November 2016
Product Code: DRF
Predicate Device for: POLARMAP™ Circular Mapping Catheter, POLARMAP™ EP Electrical Cable, SMARTFREEZE™ Esophageal ETS Cables, and SMARTFREEZE™ Pressure Sensor Cable

Reference Device: CIRCA S-CATH M Esophageal Temperature Probe and Temperature Monitoring System

Manufacturer: CIRCA Scientific, LLC
510(k) #: K200943
FDA Clearance Date: 17 December 2021
Product Code: FLL, IKD
Reference Device for: SMARTFREEZE™ Esophageal ETS Cables

IV. INDICATIONS FOR USE

POLARSHEATH™ Steerable Sheath 12F: The POLARSHEATH steerable sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart.

POLARMAP™ Circular Mapping Catheter: The POLARMAP Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

POLARMAP™ EP Electrical Cable: The EP Electrical Cable is designed for use with the POLARMAP Mapping Catheter and the hospital EP recording system. The EP Electrical Cable connects the POLARMAP Mapping Catheter to the hospital EP recording system. Use of the EP Electrical Cable is optional.

SMARTFREEZE™ ETS Cables: The Esophageal Temperature Sensor (ETS) Cable (model M004CRBS6310 or M004CRBS6320) is designed for use with the SMARTFREEZE Console and a general purpose series 400 temperature sensor. The ETS Cable is used to connect a general purpose series 400 temperature sensor to the ICB. Use of the ETS Cable is optional.

The ETS Cable (CIRCA) (model M004CRBS6340) is designed for use with the SMARTFREEZE Console and the CIRCA S-CATH™ Esophageal Temperature Probe. The ETS Cable (CIRCA) is used to connect the CIRCA S-CATH™ Esophageal Temperature Probe to the ICB (Model M004CRBS4130 only). Use of the ETS Cable (CIRCA) is optional.

NOTE: The role of esophageal temperature monitoring using this device in reducing the risk of cardiac cryoablation-related esophageal injury has not been established. The performance of the SMARTFREEZE ETS Cables and compatible temperature probe in detecting esophageal temperature changes as a result of energy delivery during cardiac cryoablation procedures has not been evaluated.

SMARTFREEZE™ Pressure Sensor Cable: The Pressure Sensor Cable is designed for use with the SMARTFREEZE Console and the cryoablation balloon catheter. The Pressure Sensor Cable is used to connect an intravascular pressure transducer to the ICB to measure the ventricular pressure during ablation procedures to aid in determining vein occlusion. Use of the Pressure Sensor Cable is optional.

V. DEVICE DESCRIPTION

The subject devices are described below.

Device	UPN/Model	Description
POLARSHEATH™ Steerable Sheath 12F	M004CRBS3150	Single-use, steerable percutaneous introducer sheath designed for additional maneuverability of diagnostic and therapeutic catheters that are advanced through the POLARSHEATH™ Sheath and into cardiac chambers.
POLARMAP™ Circular Mapping Catheter	M004CRBS7210	Single-use, multi-electrode catheter designed to record intracardiac electrograms and provide pacing stimulation during electrophysiology procedures.
POLARMAP™ EP Electrical Cable	M004CRBS62000	Single-use electrical cable that connects the POLARMAP™ mapping catheter to the hospital EP recording system.
SMARTFREEZE™ Esophageal Temperature Sensor (ETS) Cable	M004CRBS6310	Re-usable cables used to connect a temperature probe to the Inter Connection Box (ICB); used for continuous temperature monitoring during ablation procedures (optional).
SMARTFREEZE™ 16 PIN Esophageal Temperature Sensor (ETS) Cable	M004CRBS6320	

SMARTFREEZE™ CIRCA Esophageal Temperature Sensor (ETS) Cable	M004CRBS6340	
SMARTFREEZE™ Pressure Sensor Cable	M004CRBS6600	Re-usable cable that connects an intravascular pressure transducer to the ICB. The pressure sensor is used to measure the ventricular pressure during ablation procedures to aid in determining vein occlusion.

VI. SUBSTANTIAL EQUIVALENCE & COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Comparison of Subject POLARSHEATH™ Steerable Sheath 12F versus Predicate Flexcath Advance Steerable Sheath 12F (Medtronic)

Characteristic	Predicate Device (K123591) Flexcath Advance Steerable Sheath 12F (Medtronic Cryocath LP)	Subject Device POLARSHEATH™ Steerable Sheath 12F (Boston Scientific Corporation)
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 POLARSHEATH™ steerable sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart.
Sheath Usable Length	65cm	68cm
Dilator Overall Length	87cm	87cm
Guidewire Compatibility	0.81mm and 0.89mm	0.81mm and 0.89mm
Radiopaque Markers	Yes	Yes
Distal End	Unidirectional deflection curve	Unidirectional deflection curve
Shaft Design	Deflectable shaft with single lumen	Deflectable shaft with single lumen
Hemostasis Valve	Yes	Yes
Compatible Catheter Size	Facilitates use with catheters up to 10.5F in diameter	Facilitates use with catheters up to 11.8F in diameter
Materials	Pebax with stainless steel braid and PTFE liner Silicone Rubber Polycarbonate Polyethylene	Pebax with stainless steel braid and PTFE liner Silicone Rubber Polycarbonate Polyethylene
Packaging	Tyvek/nylon polyethylene pouch	Tyvek/nylon polyethylene pouch

Characteristic	Predicate Device (K123591) Flexcath Advance Steerable Sheath 12F (Medtronic Cryocath LP)	Subject Device POLARSHEATH™ Steerable Sheath 12F (Boston Scientific Corporation)
Sterilization	Provided sterile (Ethylene Oxide)	Provided sterile (Ethylene Oxide)
Single Use or Reusable	Single use	Single use

Comparison of Subject POLARMAP™ Circular Mapping Catheter versus Predicate Achieve Advance Mapping Catheter (Medtronic)

Characteristic	Predicate Device (K162892) Achieve Advance Mapping Catheter (Medtronic, Inc.)	Subject Device POLARMAP™ Circular Mapping Catheter (Boston Scientific Corporation)
Indications for Use	The Achieve Advance mapping catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Achieve Advance mapping catheter is designed to obtain electrograms in the atrial regions of the heart.	The POLARMAP Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.
Shaft Size	3.3F (1.10mm)	3.3F (1.10mm)
Effective Length	146 cm	149 cm
Ring Electrode Width	1 mm	1 mm
Loop Diameter	20 mm (15mm and 25 mm also)	20 mm
Number of Ring Electrodes	8 (20 mm loop diameter configuration)	8
Distal End Shape	Circular Loop	Circular Loop
Steering	Non-steerable	Non-steerable
Materials	Pebax (distal body) Polyimide (proximal) Nitinol insulated with PET	Pebax (distal shaft) Stainless steel (hypotube) Nitinol insulated with PET
Packaging	Individually packaged(box)	Individually packaged (carton)
Sterilization	Provided sterile (Ethylene Oxide)	Provided sterile (Ethylene Oxide)
Single Use or Reusable	Single use	Single use

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The non-clinical performance testing included in this 510(k) application provides evidence that the subject devices conform to user needs and intended use and are thus substantially equivalent to the predicates previously cleared under K123591 and K162892. No new safety or effectiveness issues were raised during device performance testing. The following test data is provided in this 510(k) application:

- Sterilization validation and EO residual assessment for the sterile POLARSHEATH™ Steerable Sheath 12F, POLARMAP™ Circular Mapping Catheter, and POLARMAP™ EP Electrical Cable
- Biocompatibility assessment and testing for the patient-contacting components of POLARSHEATH™ Steerable Sheath 12F and POLARMAP™ Circular Mapping Catheter devices
- Performance Testing per IEC 60601-1: Medical electrical equipment – Part 1 and IEC 60601-1-2: Medical electrical equipment Part 1-2
- Design verification testing of the devices and device packaging, demonstrating that the devices (and device packaging, if required/applicable) meet their design input requirements as per the product and/or packaging specifications Design verification testing at nominal (T=0) timepoint
- Design verification testing at accelerated and/or real-time aging timepoints for devices with a labeled shelf life:
    - T=12 months for POLARSHEATH™ Steerable Sheath 12F
    - T=24 months for POLARMAP™ Circular Mapping Catheter and POLARMAP™ EP Electrical Cable
- Design validation testing summary demonstrating that the POLARSHEATH™ Steerable Sheath 12F and POLARMAP™ Circular Mapping Catheter (including the POLARMAP™ EP Electrical Cable) conform to user needs and intended uses

VIII. CONCLUSION

Based on the intended use, fundamental technological characteristics, and performance testing, the proposed POLARSHEATH™ Steerable Sheath 12F, POLARMAP™ Circular Mapping Catheter, POLARMAP™ EP Electrical Cable, SMARTFREEZE™ Esophageal Temperature Sensor (ETS) Cables, and SMARTFREEZE™ Pressure Sensor Cable have been shown to be substantially equivalent to their respective predicate devices.