February 8, 2022

Shanghai MicroPort EP MedTech Co., Ltd.
Tian Xia
RA Engineer
Building 23&28, Lane 588, Tianxiong Rd.
Shanghai, Shanghai 201318
China

Re: K211530
Trade/Device Name: PathBuilder Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 29, 2021
Received: January 10, 2022

Dear Tian Xia:

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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: 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)*
K211530

Device Name
PathBuilder Steerable Introducer

Indications for Use *(Describe)*
The PathBuilder Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum

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.

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510(k) # K211530

510(k) Summary

Submitter Information

A. Company Name:	Shanghai MicroPort EP MedTech Co., Ltd.
B. Company Address:	Building 23&28, Lane 588, Tianxiong Rd., 201318 Shanghai, PEOPLE'S REPUBLIC OF CHINA
C. Company Phone:	+86 21 38954600*3613
D. Company Facsimile:	+86 21 20903925
E. Email:	txia@everpace.com
F. Contact Person:	Xia, Tian
G. Summary Prepared on:	October 20, 2021

Identification of Proposed Device

A. Trade Name:	PathBuilder™ Steerable Introducer
B. Common Name:	Catheter Introducer
C. Classification Name:	Introducer, Catheter
D. Regulation Number	21 CFR 870.1340
E. Product Code:	DYB
F. Device Class:	Class II
G. Review Panel	Cardiovascular
H. 510(k) Number	K211530

Device Description

PathBuilder™ Steerable Introducer is composed of a steerable sheath, a dilator and a guidewire. It is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The steerable sheath is introduced into a body vessel, along with the dilator, over the guidewire, it is available in a variety of lengths, sizes and curve configurations; Dilator is assembled with the sheath and introduced into a body vessel over the guidewire. It is used to provide support to the sheath and ensure smooth advancement; the guidewire is percutaneously placed into the body vessel to function as a guide for the introduction into the chambers of the heart.

The distal end of steerable sheath is embedded with a marker band and vent holes. The steerable sheath is finished at the proximal end with a hemostasis valve and sideport with a three-way stopcock. By turning the rotating collar on handle, the steerable sheath can be bidirectionally bended to facilitate the steerable sheath to reach complex heart structures more conveniently. The distal end of dilator has a tip, while its proximal end is connected with luer fitting. The inner diameter of dilator distal end is smaller than the main body for the purpose of locking the position of a puncture needle. The distal end of

dilator has a fixed curve to adapt to the heart structure.

The steerable introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. A handle equipped with a rotating collar to deflect the tip clockwise ≥180° and counter-clockwise ≥90°. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization.

Intended Use Statement

The PathBuilder™ Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Identification of Predicate Device

A.	Product Name:	Agilis™ NxT Steerable Introducer
B.	Manufacturer:	St. Jude Medical
C.	510(k) Number:	K081645
D.	Regulation Number	21 CFR 870.1340
E.	Product Code:	DYB
F.	Device Class:	Class II

Non-Clinical Performance Testing

Non-clinical performance testing was completed for the PathBuilder™ Steerable Introducer to support its substantial equivalence to the predicate device. The test results demonstrated that the proposed device complies with the following standards and guidance:

(1) Biocompatibility Verification: The biological safety of the introducer was verified as per the requirements of ISO 10993-1:2018 Biological evaluation of medical devices- Part 1:Evaluation and testing within a risk management process and FDA's modified ISO guidelines in accordance with the FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

a) Cytocompatiblity

b) Sensitization

c) Irritation

d) Acute Systemic Toxicity

e) Hemocompatibility

f) Complement Activation

g) Thrombogenicity

(2) Bench Validation: Validation testing of the introducer was performed to validate the design of the device . This testing included visual inspection, dimensional verification, packaging testing (visual inspection, sealing strength, dye penetration), transit testing and mechanical failure/performance (Peak tensile force of joints, flexion testing and fracture testing of guidewire). Additionally, the compatibly of the of the introducer, guidewire and dilator was validated with compatibility, bending load, controlling curve force, insertion withdrawal force, pushing force, simulated use fatigue testing (put the device through repeated physiologically relevant turns and observed for damage), radio detectability, freedom from leakage, dilator hub and 3-way stopcock Luer testing. All samples were sterilized and aged prior to testing. All tested samples passed bench testing.

(3) Cleaning and Sterilization Validation: Validation testing was performed to demonstrate that the introducer could be sterilized in accordance with ISO 11135:2014 Sterilization of health care products-Ethylene Oxide: Requirements for development, validation and routine control of a sterilization process for medical device, AAMI TIR 28:2009 Product Adoption and Process Equivalency for Ethylene Oxide sterilization and the FDA guidance document.

(4) Shelf Life Validation: Validation testing was performed to demonstrate the shelf life of the introducer is three years.

Clinical Tests Conclusion

No clinical study was used to support this submission.

Comparison to Predicate Device

Description	Proposed Device	Predicate Device (K081645)	Remark
Product Code	DYB	DYB	SE
Regulation No.	21 CFR 870.1340	21 CFR 870.1340	SE
Class	Class II	Class II	SE
Intended Use	The PathBuilder™ Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of	The Agilis™ NxT Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of	SE

	the heart through the interatrial septum.	the heart through the interatrial septum.	
Indications for Use	The PathBuilder™ Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	The Agilis™ NxT Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.	SE
Configuration	Steerable sheath	Steerable sheath	SE
	Dilator	Dilator	SE
	Guidewire	Guidewire	SE
Functional performance	Comply with ISO 11070: 2014	Comply with ISO 11070: 2014	SE
Biological characteristics	Comply with ISO 10993-1	Comply with ISO 10993-1	SE
Dimensional Comparision	Total length of steerable sheath	Total length of steerable sheath	SE
	Outer diameter of steerable sheath	Outer diameter of steerable sheath	SE
	Inner diameter of steerable sheath tip	Inner diameter of steerable sheath tip	SE
	Curve shape of steerable sheath tip	Curve shape of steerable sheath tip	SE
	Effective length of dilator	Effective length of dilator	SE
	Outer diameter of dilator	Outer diameter of dilator	SE
	Inner diameter of dilator tip	Inner diameter of dilator tip	SE
	Curve shape of dilator tip	Curve shape of dilator tip	SE
	Effective length of guidewire	Effective length of guidewire	SE
	Outer diameter of guidewire	Outer diameter of guidewire	SE
	Inner diameter of J-curve tip	Inner diameter of J-curve tip	SE
Intended healthcare environment	Professional healthcare environment	Professional healthcare environment	SE
Sterilization method	EO Sterilized	EO Sterilized	SE
Single use	Yes	Yes	SE
Shelf Life	3 years	3 years	SE

Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.

The proposed and predicate devices share the same intended use and fundamental scientific technology, including principles of operation and mechanism of action. Design and technological differences between the proposed and predicate devices do not raise any new concerns of safety and effectiveness. The results of verification and validation testing demonstrate that the PathBuilder™ Steerable Introducer is substantially equivalent to the predicate device.