December 30, 2022

Shanghai MicroPort EP MedTech Co., Ltd.
Min Zhu
RA Engineer
Building 23&28, Lane 588, Tianxiong Rd.
Shanghai, Shanghai 201318
People's Republic of China

Re: K210313
Trade/Device Name: EasyFinder™ Fixed Curve Diagnostic Catheter; FORLNK™ Cable for Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: DRF
Dated: January 25, 2021
Received: February 3, 2021

Dear Xia Tian:

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,

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)*
K210313

Device Name
EasyFinder™ Fixed Curve Diagnostic Catheter
FORLNK™ Cable for Mapping Catheter

Indications for Use *(Describe)*
EasyFinder™ Fixed Curve Diagnostic Catheter is used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies.

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) 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*53701
D. Company Facsimile:	+86 21 20903925
E. Email:	zhumin@everpace.com
F. Contact Person:	Zhu, Min
G. Summary Prepared on:	December 30, 2022

Identification of Proposed Device

A. Device Trade Name:	EasyFinder™ Fixed Curve Diagnostic Catheter FORLNK™ Cable for Mapping Catheter
B. Device Common Name:	Electrode recording catheter
C. Classification Name:	Catheter, Electrode Recording, Or Probe, Electrode Recording
D. Regulation Number	21 CFR 870.1220
E. Product Code:	DRF
F. Device Class:	Class II
G. Review Panel	Cardiovascular

Device Description

The EasyFinder™ Fixed Curve Diagnostic Catheter is a sterile, single-use diagnostic catheter with multiple electrodes and a fixed distal curve. It has been designed to facilitate electrophysiological mapping of cardiac structures in 28 models and 6 kinds of curves.

The catheter has a high-torque shaft with a fixed curve section containing an array of platinum electrodes. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

The catheter is connected to separately cleared diagnostic electrophysiology equipment via an accessory, the FORLNK™ Cable for Mapping Catheter.

Indications for Use Statement

EasyFinder™ Fixed Curve Diagnostic Catheter is used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies.

Identification of Predicate Device

A. Product Name:	IBI-1100(TM) ELECTROPHYSIOLOGY CATHETER

B. Manufacturer: IRVINE BIOMEDICAL, INC.
C. 510(k) Number: K946333
D. Regulation Number 21 CFR 870.1220
E. Product Code: DRF
F. Device Class: Class II

Identification of Reference Device

A. Product Name: Cordis Webster Fixed Curve Catheter
B. Manufacturer: Cordis Webster, Inc.
C. 510(k) Number K992965
D. Regulation Number 21 CFR 870.1220
E. Product Code: DRF
F. Device Class: Class II

Non-Clinical Performance Testing

Non-clinical performance testing was completed for the EasyFinder™ Fixed Curve Diagnostic Catheter and accessory FORLNK™ Cable for Mapping Catheter to support their substantial equivalence to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

(1) Biocompatibility Verification: The biological safety of the catheter 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".

(2) Mechanical Verification: Mechanical testing was performed to verify compliance of the catheter with ISO 10555-1:2013 Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements.

(3) Electrical Verification: Electrical testing was performed to verify compliance of the catheter and accessory cable with applicable IEC 60601-1: 2005 Medical electrical equipment – Part1: General requirements for basic safety and essential performance, IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests and IEC 60601-2-27:2011 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.

(4) Bench Validation: Validation testing of the catheter was performed to validate the design of the device with regards to radiopacity. Validation testing of the accessory cable was performed to evaluate the design and function of the cable.

(5) Cleaning and Sterilization Validation: Validation testing was performed to demonstrate that the catheter and accessory cable could be cleaned and 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.

(6) Shelf Life Validation: Validation testing was performed to demonstrate the shelf life of the catheter and accessory cable are three years.

Clinical Tests Conclusion

No clinical study is included in this submission.

Comparison to Predicate Device

Description	Proposed Device	Predicate Device (K946333)	Remark
Product Code	DRF	DRF	SE
Regulation No.	21 CFR 870.1220	21 CFR 870.1220	SE
Class	Class II	Class II	SE
Indications for Use	EasyFinder™ Fixed Curve Diagnostic Catheter is used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies.	IBI-1100(TM) ELECTROPHYSIOLOGY CATHETER is used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies.	SE
Configuration	Cable connector	Cable connector	SE
	Tip electrode	Tip electrode	SE
	Ring electrode	Ring electrode	SE
	High-torque shaft	High-torque shaft	SE
Dimensional Comparison	Catheter effective length	Catheter effective length	Similar
	Length of color code	Length of color code	SE
	Electrode length	Electrode length	Similar
	Electrode diameter	Electrode diameter	SE
	Electrode spacing	Electrode spacing	SE

	Outside diameter of catheter shaft	Outside diameter of catheter shaft	SE
	Curve shape	Curve shape	Similar
Functional Performance	Comply with ISO 10555-1	Comply with ISO 10555-1	SE
Biological Characteristics	Comply with ISO 10993-1	Comply with ISO 10993-1	Similar
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 indications for 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 EasyFinder™ Fixed Curve Diagnostic Catheter and the accessory cable are as safe, as effective, and perform in a manner that is substantially equivalent to the predicate device.