April 7, 2026

Shanghai MicroPort Medical (Group) Co., Ltd.
Huasheng Li
Regulatory Affairs
1601 Zhangdong Road, ZJ Hi-Tech Park
Shanghai, Shanghai 201203
China

Re: K252116
Trade/Device Name: Firefighter™ Pro PTCA Balloon Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (Ptca) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: July 3, 2025
Received: July 7, 2025

Dear Huasheng Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JENNY R. KATSNELSON -S

Digitally signed by JENNY R. KATSNELSON -S
Date: 2026.04.07 15:50:42 -04'00'

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252116

Device Name
Firefighter Pro PTCA Balloon Catheter

Indications for Use *(Describe)*
Firefighter Pro PTCA Balloon Catheter is indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

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 – K252116

Submitter's Name and Address:	Shanghai MicroPort Medical (Group) Co., Ltd. 1601 Zhangdong Road, ZJ Hi-Tech Park Shanghai Shanghai 201203 China
Contact Person:	Huasheng Li Regulatory affairs Shanghai MicroPort RotaPace MedTech Co., Ltd. Room 1516, Floor 15, Building 1, No.1601 Zhangdong Road, ZJ Hi-Tech Park, 201203 Shanghai, PEOPLE'S REPUBLIC OF CHINA Phone: +86-21-38954600 Fax: 86-021-50801305 Email: huasheng.li@microport.com
Date Prepared	March 31, 2026
Trade Name:	Firefighter™ Pro PTCA Balloon Catheter
Common Name:	Percutaneous Catheter
Classification:	Class II, 21 CFR Part 870.5100
Product Code:	LOX
Predicate Device:	TREK™ & MINI TREK™ RX Coronary Dilatation Catheter (K180040)
Device Description:	Firefighter™ Pro PTCA Balloon Catheter (hereinafter Firefighter™ Pro) is a rapid exchange catheter, with a semi-compliant balloon near the distal tip. The device is assembled by the distal section and the proximal section. The distal section is a dual-lumen shaft arranged coaxially to enable the rapid exchange capability. The inner lumen of the catheter accommodates guidewires with a diameter of ≤0.014 inch (0.36mm). The distal section is fabricated by non-toxic and biocompatible polymer, coated with PVP hydrophilic coating. The hydrophilic coating is located on the whole distal section to reduce friction and enhance crossing capability. The length of hydrophilic coating is 405mm. The effective length of the balloon catheter is approximately 145 cm.
Indications for Use:	Firefighter™ Pro PTCA Balloon Catheter is indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
Comparison with Predicate Device:	The Firefighter™ Pro is similar to the TREK™ & MINI TREK™ RX in the following ways: • Same rapid exchange design; • Same catheter design;

	• Same compatibility with the guide wire; • Same method of sterilization (EO); The Firefighter™ Pro is different to the TREK™ & MINI TREK™ RX in the following ways: • Balloon diameters and balloon lengths • Shelf life • Balloon nominal and rated burst pressure • Catheter materials
Performance Data:	Biocompatibility Testing The biocompatibility evaluation for the Firefighter™ Pro was conducted in accordance with current standards and included the following tests: • Cytotoxicity • Sensitization • Irritation/Intracutaneous Reactivity • Systemic Toxicity (acute) • Pyrogen Study (Material Mediated) • Hemocompatibility (Hemolysis, Complement Activation Assay and Thrombogenicity) Bench Testing Mechanical testing was performed per the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (issued by FDA in September 2010) on the subject device. The tests included the following: • Dimensional verification • Balloon Preparation, Deployment and Retraction • Balloon Rated Burst Pressure • Balloon Fatigue (Repeat Balloon Inflations) • Balloon Compliance (Diameter vs. Pressure) • Balloon Inflation and Deflation Time • Catheter Bond Strength • Tip Pull Test • Flexibility and Kink Test • Torque Strength • Radiopacity • Coating Integrity • Particulate Evaluation

	• Endotoxin • Corrosion resistance • Freedom from leakage
Conclusion:	The nonclinical tests of the Firefighter™ Pro demonstrate that the device is substantially equivalent to the legally marketed device predicate as per 21 CFR 807.92(b) (3).