July 21, 2023

Shanghai MicroPort Medical (Group) Co., Ltd.
℅ Yutian Yang
Advanced Supervisor of Regulatory Affairs Department
MicroPort Sinica Co., Ltd.
1601 ZhangDong Rd, ZJ Hi-Tech Park
Shanghai, Shanghai 201203
China

Re: K223189
Trade/Device Name: Firefighter™ NC 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: June 14, 2023
Received: June 15, 2023

Dear Yutian Yang:

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.07.21 09:23:39 -04'00'

Gregory O'Connell
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223189

Device Name
Firefighter™ NC Pro PTCA Balloon Catheter

Indications for Use *(Describe)*
Firefighter™ NC Pro PTCA Balloon Catheter is indicated to be used for:

- Balloon dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion;
- Balloon dilatation of post-delivery expansion of balloon expandable stents (models 2.00-5.00mm).

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

Sponsor:	Shanghai MicroPort Medical (Group) Co., Ltd 1601 Zhangdong Road, ZJ Hi-Tech Park, 201203 Shanghai, PEOPLE'S REPUBLIC OF CHINA
Contact Person:	Xia Tian Phone: 86-021-38954600 Fax: 86-021-50801305 Email: Xia.Tian@microport.com
Date Prepared:	July 17th, 2023
Trade Name:	Firefighter™ NC Pro PTCA Balloon Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification:	Class II, 21 CFR Part 870.5100
Product Code:	LOX
Predicate Device:	K141236 – NC Emerge™ Monorail™ PTCA Dilatation Catheter (Boston Scientific Corporation) *This predicate device has not been subject to a design-related recall.*
Device Description:	Firefighter™ NC Pro PTCA Balloon Catheter is a rapid exchange catheter, with a non-compliant balloon near the distal tip. Two radiopaque marker bands are located underneath the balloon and fixed on the inner lumen to position the balloon. The hydrophilic coating is located on the whole distal section to reduce friction and enhance the crossing capability. The effective length of the catheter is 145cm, the inner lumen of catheter permits the use of guide wire ≤ 0.014 inch (0.36mm). Firefighter™ NC Pro is available with balloon diameters of 2.00-5.50mm and balloon lengths of 6, 10, 15, 20, 25 and 30mm. 5F Guiding catheter is used for the delivery of Firefighter™ NC Pro with 2.00-4.00mm balloon diameter. 6F Guiding catheter is used for the delivery of Firefighter™ NC Pro with 4.50-5.50mm balloon diameter.
Indications for Use:	Firefighter™ NC Pro PTCA Balloon Catheter is indicated to be used for: • Balloon dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion; • Balloon dilatation of post-delivery expansion of balloon expandable stents (models 2.00-5.00mm).

Comparison with Predicate Device: The Firefighter™ NC Pro PTCA Balloon Catheter is similar to the predicate device in the components, design, materials, sterility, shelf life and operating principle. The indications for use of the subject device and the predicate device are the same.

Item	Subject device	Predicate device	Comparison
Name	Firefighter™ NC Pro PTCA Balloon Catheter	NC Emerge™ Monorail™ PTCA Dilatation Catheter	N/A
510(k) number	K223189	K141236	N/A
Manufacturer	Shanghai MicroPort Medical (Group) Co., Ltd	Boston Scientific Corporation	N/A
Indications for use	Firefighter™ NC Pro PTCA Balloon Catheter is indicated to be used for: • Balloon dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion; • Balloon dilatation of post-delivery expansion of balloon expandable stents (models 2.00-5.00mm).	The NC Emerge Monorail (MR) and NC Emerge Over-The-Wire (OTW) PTCA Dilatation Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a native coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion in patients with atherosclerosis. NC Emerge Over-The-Wire and NC Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-5.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).	Same
Catheter effective length	145 cm	143 cm	Substantially equivalent
Recommended guide catheter	Ø 2.00-4.00mm: 5F Ø 4.50-5.50mm: 6F	Ø 2.00-4.00mm: Minimum I.D. of GC=0.056in (1.42mm) Ø 4.50-5.50mm: Minimum I.D. of GC=0.066in (1.68mm)	Substantially equivalent
Recommended guide wire	0.014” (0.36 mm)	0.014” (0.36 mm)	Same
Rapid exchange design	Yes	Yes	Same
Hydrophilic coating	Yes	Yes	Same

Sterility	Sterile	Sterile	Same
Shelf life	2 years	2 years	Same
Single use	Yes	Yes	Same
Radiopaque marker bands	Yes (2; platinum iridium)	Yes (2; platinum iridium)	Same
Proximal shaft depth markers	Yes	Yes	Same
Balloon diameters	• 2.00-4.00 mm (in 0.25 mm increments) • 4.50 mm • 5.00 mm • 5.50 mm	• 2.00-4.00 mm (in 0.25 mm increments) • 4.50 mm • 5.00 mm • 5.50 mm • 6.00 mm	Substantially equivalent
Balloon lengths	6, 10, 15, 20, 25, 30 mm	6, 8, 12, 15, 20, 30 mm	Substantially equivalent
Balloon nominal pressure	12.0 atm	12.0 atm	Same
Balloon rated burst pressure	• 20 atm for 2.00-4.00 mm diameter balloons • 18 atm for 4.50-5.50 mm diameter balloons	• 20 atm for 2.00-4.00 mm diameter balloons • 18 atm for 4.50-6.00 mm diameter balloons	Substantially equivalent

Performance Data:

Biocompatibility Testing

The biocompatibility evaluation for the Firefighter™ NC Pro device was conducted in accordance with current standards and included the following tests:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Systemic Toxicity (acute)
- Pyrogen Study (Material Mediated)
- Haemocompatibility
  - Direct and Indirect Hemolysis
  - Complement Activation
  - *In vivo* Thrombogenicity in Canine

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 • Balloon Rated Burst Pressure (in Stent) • Balloon Fatigue (Repeat Balloon Inflations; in Stent) • Endotoxin • Freedom from Leakage • Corrosion Resistance • Balloon preparation, Deployment and Retraction (in Stent) • Coating Integrity (in Stent) • Particulate Evaluation (in Stent)
Conclusion:	Based on the data provided, the Firefighter™ NC Pro PTCA Balloon Catheter does not raise new questions of safety and effectiveness and is substantially equivalent to the predicate device.