

K223189 Firefighter™ NC Pro PTCA Balloon CatheterJul 21, 2023
282 days to decisionK223189 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k223189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Oct 12, 2022
Decision date	Jul 21, 2023
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai MicroPort Medical (Group) Co., Ltd.
Location	Shanghai, CN
Contact	Xia Tian
510(k) history	3 submissions · 3 cleared · 2015-2026

REGULATORY CONSULTANT

Consulting firm	Microport Sinica Co., Ltd.
Contact	Yutian Yang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223189/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026