

**K252116 Firefighter™ Pro PTCA Balloon Catheter**Apr 7, 2026  
274 days to decisionK252116 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k252116/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jul 7, 2025
Decision date	Apr 7, 2026
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai MicroPort Medical (Group) Co., Ltd.</b>
Location	Shanghai, CN
Contact	Huasheng Li
510(k) history	3 submissions · 3 cleared · 2015-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252116/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026