

**K070532 SPIROS**Mar 20, 2007  
22 days to decisionK070532 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k070532/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 26, 2007
Decision date	Mar 20, 2007
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Icu Medical, Inc.</b>
Location	Walker, MI, US
Contact	MARTIN MAIER
510(k) history	66 submissions · 65 cleared · 1984-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k070532/> 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 June 28, 2026