

**K950118 ABRM CATHETER**Feb 8, 1996  
393 days to decisionK950118 · Product code: **FOZ** · General Hospital  
Source: <https://www.510kdatabase.net/k950118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Jan 11, 1995
Decision date	Feb 8, 1996
Days to decision	393 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cook, Inc.</b>
Location	Mchenry, IL, US
Contact	APRIL LAVENDER
510(k) history	190 submissions · 179 cleared · 1976-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950118/> 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 14, 2026