

**K911251 FLEX-IV**Oct 28, 1991  
221 days to decisionK911251 · Product code: **FOZ** · General Hospital  
Source: <https://www.510kdatabase.net/k911251/>**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	Mar 21, 1991
Decision date	Oct 28, 1991
Days to decision	221 days
Third-party review	No

**APPLICANT**

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Company	<b>Medway</b>
Location	Franklin, TN, US
Contact	JAMES J CALLAWAY
510(k) history	5 submissions · 5 cleared · 1991-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911251/>, 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 26, 2026