

**K852078 SPECTRUM(TENTATIVE)**Jun 7, 1985  
25 days to decisionK852078 · Product code: **FOZ** · General Hospital  
Source: <https://www.510kdatabase.net/k852078/>**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	May 13, 1985
Decision date	Jun 7, 1985
Days to decision	25 days
Third-party review	No

**APPLICANT**

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Company	<b>Parke-Davis Co.</b>
Location	Mchenry, IL, US
Contact	CLEARY
510(k) history	47 submissions · 47 cleared · 1976-1986

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852078/>; 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 27, 2026