

**K921860 MODIFICATION TO IV SPIKE**Jul 30, 1992  
141 days to decisionK921860 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k921860/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 11, 1992
Decision date	Jul 30, 1992
Days to decision	141 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>McGaw, Inc.</b>
Location	Irvine, CA, US
Contact	DIANE GERST
510(k) history	13 submissions · 13 cleared · 1991-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921860/> 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 30, 2026