

**K972663 SMART SET**Sep 2, 1997  
56 days to decisionK972663 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k972663/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 8, 1997
Decision date	Sep 2, 1997
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Top Spins, Inc.</b>
Location	Ann Arbor, MI, US
Contact	MARTIN R PRINCE
510(k) history	3 submissions · 3 cleared · 1997-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972663/> 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 18, 2026