

**K970800 MAXCESS NEEDLEFREE - Y- SITE (100713)**Apr 2, 1997  
29 days to decisionK970800 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k970800/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 4, 1997
Decision date	Apr 2, 1997
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Solopak Medical Products, Inc.</b>
Location	Libertyville, IL, US
Contact	ELIZABETH LOYA
510(k) history	4 submissions · 4 cleared · 1996-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970800/> 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 July 6, 2026