

**K021395 MODIFICATION TO 30 EXTENSION SET**May 13, 2002  
11 days to decisionK021395 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k021395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 2, 2002
Decision date	May 13, 2002
Days to decision	11 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Churchill Medical Systems, Inc.</b>
Location	Horsham, PA, US
Contact	KEVIN PALUCH
510(k) history	12 submissions · 12 cleared · 1988-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021395/> 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 2, 2026