

**K012429 SURESET INFUSION SET, MODEL 8023**Nov 6, 2001  
98 days to decisionK012429 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k012429/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Jul 31, 2001
Decision date	Nov 6, 2001
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Applied Diabetes Research, Incorporated</b>
Location	Chapel Hill, NC, US
Contact	CHARLES H KYPER
510(k) history	3 submissions · 3 cleared · 2001-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012429/> 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