

**K941151 STRATOFUSE PCA II INFUSER**Jul 7, 1994  
118 days to decisionK941151 · Product code: **FRN** · General HospitalSource: <https://www.510kdatabase.net/k941151/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Mar 11, 1994
Decision date	Jul 7, 1994
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infusion Technology Intl.</b>
Location	Danvers, MA, US
Contact	PAUL FENTON
510(k) history	3 submissions · 3 cleared · 1994-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941151/> 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