

**K921901 PORT ACCESS INFUSION SET**Sep 10, 1993  
506 days to decisionK921901 · Product code: **FRN** · General Hospital  
Source: <https://www.510kdatabase.net/k921901/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Apr 22, 1992
Decision date	Sep 10, 1993
Days to decision	506 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Kawasumi Laboratories Co., Ltd.</b>
Location	Canoga Park, CA, US
Contact	SHOZO MORIYAMA
510(k) history	18 submissions · 18 cleared · 1987-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921901/> 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 June 30, 2026