

K970485 SMARTSITE ACCESS PINApr 21, 1997
70 days to decisionK970485 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k970485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 10, 1997
Decision date	Apr 21, 1997
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ivac Medical Systems
Location	San Diego, CA, US
Contact	RENEE L FLUET
510(k) history	2 submissions · 2 cleared · 1997-1998

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