

K980078 PENETREASEOct 16, 1998
281 days to decisionK980078 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k980078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jan 8, 1998
Decision date	Oct 16, 1998
Days to decision	281 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	P.T. Panca Pusaka Deli
Location	Chester, NY, US
Contact	JANE CAMPBELL
510(k) history	1 submissions · 1 cleared · 1998-1998

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