

**K852304 SAFE-N-JECT**Sep 20, 1985  
114 days to decisionK852304 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k852304/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	May 29, 1985
Decision date	Sep 20, 1985
Days to decision	114 days
Third-party review	No

**APPLICANT**

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Company	<b>Gerstner Intl. Trade</b>
Location	South Pasadena, CA, US
Contact	DEENA B GERSTNER
510(k) history	1 submissions · 1 cleared · 1985-1985

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852304/>; 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 9, 2026