

**K983994 UNIFINE**Jan 8, 1999  
60 days to decisionK983994 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k983994/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 9, 1998
Decision date	Jan 8, 1999
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Owen Mumford USA, Inc.</b>
Location	Marietta, GA, US
Contact	ROBERT SHAW
510(k) history	10 submissions · 10 cleared · 1995-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983994/> 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 29, 2026