

**K950245 UNIQUE NEEDLE**Dec 6, 1995  
320 days to decisionK950245 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k950245/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jan 20, 1995
Decision date	Dec 6, 1995
Days to decision	320 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Unique Management Ent., Inc.</b>
Location	Albany, NY, US
Contact	THOMNAS E FERARI
510(k) history	2 submissions · 2 cleared · 1995-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950245/> 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 6, 2026