

**K130049 MONOJECT 12ML SYRINGE**Feb 14, 2013  
37 days to decisionK130049 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k130049/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Jan 8, 2013
Decision date	Feb 14, 2013
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nipro Medical Corporation</b>
Location	Lexington, KY, US
Contact	JESSICA OSWALD-MCLEOD
510(k) history	34 submissions · 34 cleared · 2005-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130049/> 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 9, 2026