

**K033373 MONOJECT INSULIN SYRINGE**Nov 13, 2003  
22 days to decisionK033373 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k033373/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 22, 2003
Decision date	Nov 13, 2003
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tyco Healthcare</b>
Location	Mansfield, MA, US
Contact	DAVID OLSON
510(k) history	14 submissions · 14 cleared · 2001-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033373/> 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 26, 2026