

**K973339 DISETRONIC PENFINE INJECTION PEN NEEDLE**Sep 24, 1997  
19 days to decisionK973339 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k973339/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 5, 1997
Decision date	Sep 24, 1997
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Disetronic Medical Systems</b>
Location	Minnetonka, MN, US
510(k) history	17 submissions · 13 cleared · 1991-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973339/>; 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 3, 2026