

**K013782 DISETRONIC PENFINE INSULIN INJECTION PEN  
NEEDLE**Nov 20, 2001  
6 days to decisionK013782 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k013782/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 14, 2001
Decision date	Nov 20, 2001
Days to decision	6 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Disetronic Medical Systems</b>
Location	Minnetonka, MN, US
Contact	DAVID E CHADWICK
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/k013782/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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