

K982399 DISETRONIC PENFINE INJECTION PEN NEEDLEAug 6, 1998
27 days to decisionK982399 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k982399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jul 10, 1998
Decision date	Aug 6, 1998
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Disetronic Medical Systems
Location	Minnetonka, MN, US
Contact	PATRIK DE HAES
510(k) history	17 submissions · 13 cleared · 1991-2001

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