

K994197 DISENTRONIC PENFINE INJECTION PEN NEEDLEDec 29, 1999
16 days to decisionK994197 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k994197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 13, 1999
Decision date	Dec 29, 1999
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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