

K980227 MANAN GALACTOGRAPHY KITApr 23, 1998
91 days to decisionK980227 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k980227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 22, 1998
Decision date	Apr 23, 1998
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medical Device Technologies, Inc.
Location	Gainesville, FL, US
Contact	KARL SWARTZ
510(k) history	46 submissions · 46 cleared · 1992-2010

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