

K980372 MANAN VS ACCESS NEEDLE/SETApr 27, 1998
87 days to decisionK980372 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k980372/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jan 30, 1998
Decision date	Apr 27, 1998
Days to decision	87 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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