

K974815 MANAN(TM) INTRODUCER SHEATH/NEEDLEJan 9, 1998
17 days to decisionK974815 · Product code: **FGE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k974815/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 23, 1997
Decision date	Jan 9, 1998
Days to decision	17 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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