

K983765 INJECTION NEEDLE PROBE/DEVICE-TUNISDec 11, 1998
46 days to decisionK983765 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k983765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Oct 26, 1998
Decision date	Dec 11, 1998
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ximed/Prosure/Injectx
Location	San Jose, CA, US
Contact	ASHVIN DESAI
510(k) history	9 submissions · 9 cleared · 1995-2001

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