

**K000646 DISPOSABLE INJECTOR OR DISPOSABLE
SCLEROTHERAPY NEEDLE**Apr 13, 2000
48 days to decisionK000646 · Product code: **FBK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k000646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Feb 25, 2000
Decision date	Apr 13, 2000
Days to decision	48 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Enteric Medical Technologies
Location	Foster City, CA, US
Contact	JILL M VISOR
510(k) history	2 submissions · 2 cleared · 2000-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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