

K082319 INJEKT FILIFORM INJECTION NEEDLESep 25, 2008
43 days to decisionK082319 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k082319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Aug 13, 2008
Decision date	Sep 25, 2008
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Urological, Inc.
Location	Spencer, IN, US
Contact	CINDY FOOTE
510(k) history	104 submissions · 102 cleared · 1986-2011

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