

K113634 INJEKT CYSTO FLEXIBLE INJECTION NEEDLEFeb 14, 2012
67 days to decisionK113634 · Product code: **FBK** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k113634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Dec 9, 2011
Decision date	Feb 14, 2012
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Ireland, Ltd.
Location	Limerick, IE
Contact	LAURA GUINANE
510(k) history	32 submissions · 27 cleared · 2005-2024

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