

K963565 MRI NEEDLESJul 14, 1997
312 days to decisionK963565 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k963565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Sep 5, 1996
Decision date	Jul 14, 1997
Days to decision	312 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook, Inc.
Location	Mchenry, IL, US
Contact	APRIL LAVENDER
510(k) history	190 submissions · 179 cleared · 1976-2015

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