

K160423 Perineologic Access NeedleSep 2, 2016
199 days to decisionK160423 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160423/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Feb 16, 2016
Decision date	Sep 2, 2016
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Corbin Clinical Resources, LLC
Location	Cumberland, MD, US
Contact	Kenneth K. Kleinhenz
510(k) history	2 submissions · 2 cleared · 2016-2016

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