

K160890 Howell Biliary Introducer NeedleJun 14, 2017
440 days to decisionK160890 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160890/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Mar 31, 2016
Decision date	Jun 14, 2017
Days to decision	440 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical, Inc.
Location	Winstrom-Salem, NC, US
Contact	ASHLEY HOWARD
510(k) history	124 submissions · 117 cleared · 1985-2025

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