

K141894 SHARKCORE FINE NEEDLE BIOPSY SYSTEMOct 6, 2014
84 days to decisionK141894 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k141894/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jul 14, 2014
Decision date	Oct 6, 2014
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC(Formerly Beacon Endoscopic Corp.)
Location	Auburndale, MA, US
Contact	Saket Bhatt
510(k) history	2 submissions · 2 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141894/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 4, 2026