

**K150891 BNX Fine Needle Aspiration System and SharkCore
LG Fine Needle Biopsy System**May 1, 2015
29 days to decisionK150891 · Product code: **FCG** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k150891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Biopsy Needle (FCG)
Date received	Apr 2, 2015
Decision date	May 1, 2015
Days to decision	29 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/k150891/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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