

K133008 BNX DELIVERY SYSTEM PRE-LOADED WITH 19, 22 AND 25 GAUGE NEEDLE, 19, 22 OR 25 GAUGE NEEDLES (INDIVIDUALLY STERILE-PACKED,

Nov 20, 2013
56 days to decision

K133008 · Product code: **FCG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k133008/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Sep 25, 2013
Decision date	Nov 20, 2013
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beacon Endoscopic
Location	Auburndale, MA, US
Contact	ANNETTE M FAGNANT
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k133008/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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