

**K180037 Beacon EUS Access System**Apr 26, 2018  
111 days to decisionK180037 · Product code: **FCG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k180037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Jan 5, 2018
Decision date	Apr 26, 2018
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	Rachel Silva
510(k) history	88 submissions · 85 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180037/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026