

**K160845 Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device**May 3, 2016  
36 days to decisionK160845 · Product code: **ODG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k160845/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Mar 28, 2016
Decision date	May 3, 2016
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Yingying Gao
Website	<a href="https://www.bostonscientific.com">https://www.bostonscientific.com</a>
510(k) history	229 submissions · 216 cleared · 2005-2026

Boston Scientific Corporation is a global medical device manufacturer headquartered in Marlborough, Massachusetts. The company develops and markets devices across multiple medical specialties. Boston Scientific has received FDA 510(k) clearances from total submissions since its first clearance in 2005. The company maintains active regulatory engagement, with the latest clearance in 2026. Its cleared devices span cardiovascular, radiology, gastroenterology, urology, and surgical specialties, reflecting a broad portfolio of interventional and diagnostic technologies. Recent...

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