

**K163058 Expect Slimline (SL) Endoscopic Ultrasound  
Aspiration Needle**Jan 30, 2017  
90 days to decisionK163058 · Product code: **ODG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k163058/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Nov 1, 2016
Decision date	Jan 30, 2017
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Scientific</b>
Location	San Jose, CA, US
Contact	Jennifer Edouard
Website	<a href="http://www.bostonscientific.com/">http://www.bostonscientific.com/</a>
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k163058/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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