

K173184 Expect Slimline (SL) Endoscopic Ultrasound Aspiration Needle

Oct 27, 2017
28 days to decisionK173184 · Product code: **ODG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k173184/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Sep 29, 2017
Decision date	Oct 27, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	Jennifer Edouard
Website	http://www.bostonscientific.com/
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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