

K140323 NAVIGATOR HD URETERAL ACCESS SHEATH SETSMar 7, 2014
25 days to decisionK140323 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k140323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Feb 10, 2014
Decision date	Mar 7, 2014
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	NICHOLE RIEK
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. ...
