

**K250517 Navigator™ HD Ureteral Access Sheath Set 11/13 F x 28cm (M0062502210)**Mar 21, 2025  
28 days to decisionK250517 · Product code: FED · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k250517/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Feb 21, 2025
Decision date	Mar 21, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Navigator™ HD Ureteral Access Sheath Set 11/13 F x 36cm (M0062502220); Navigator™ HD Ureteral Access Sheath Set 11/13 F x 46cm (M0062502230); Navigator™ HD Ureteral Access Sheath Set 12/14 F x 28cm (M0062502240); Navigator™ HD Ureteral Access Sheath Set 12/14 F x 36cm (M0062502250); Navigator™ HD Ureteral Access Sheath Set 12/14 F x 46cm (M0062502260); Navigator™ HD Ureteral Access Sheath Set 13/15 F x 28cm (M006

**APPLICANT**

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Timilehin Adenekan
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...