

K122649 NAVIGATOR HD URETERAL ACCESS SHEATH SETDec 12, 2012
104 days to decisionK122649 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k122649/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Access Overtube, Gastroenterology-urology (FED) |
| Date received | Aug 30, 2012 |
| Decision date | Dec 12, 2012 |
| Days to decision | 104 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------------------------------------------------|
| Company | Boston Scientific Corp |
| Location | San Jose, CA, US |
| Contact | HUDA YUSUF |
| Website | https://www.bostonscientific.com/ |
| 510(k) history | 432 submissions · 411 cleared · 1988-2024 |

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...
