

K251291 Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers

Jul 3, 2025
69 days to decision

K251291 · Product code: FGE · Gastroenterology & Urology

Source: <https://www.510kdatabase.net/k251291/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 25, 2025
Decision date	Jul 3, 2025
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	Yanine Garcia-Quezada
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. ...