

## K223592 Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers

Dec 29, 2022  
28 days to decisionK223592 · Product code: FGE · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k223592/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 1, 2022
Decision date	Dec 29, 2022
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Boston Scientific Corporation</b>
Location	Marlborough, MA, US
Contact	Kerri LaPlaca
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...