

K260428 RIVOS™ EUS Access Device (M00553900)Jun 17, 2026
127 days to decisionK260428 · Product code: **ODG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k260428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Ultrasound System, Gastroenterology-urology (ODG)
Date received	Feb 10, 2026
Decision date	Jun 17, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	Yingying Gao
Website	https://www.bostonscientific.com
510(k) history	232 submissions · 219 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...