

K262406 EluPro Antibiotic-Eluting BioEnvelope

Aug 12, 2026
28 days to decision

K262406 · Product code: FTM · Cardiovascular
Source: <https://www.510kdatabase.net/k262406/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	Jul 15, 2026
Decision date	Aug 12, 2026
Days to decision	28 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	Cary Percy
Website	http://www.bostonscientific.com/
510(k) history	60 submissions · 54 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. ...