

K152572 AXIOS Stent and Delivery SystemOct 6, 2015
27 days to decisionK152572 · Product code: **PCU** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k152572/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Pancreatic Stent, Covered, Metallic, Removable (PCU) |
| Date received | Sep 9, 2015 |
| Decision date | Oct 6, 2015 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Corporation |
| Location | Marlborough, MA, US |
| Contact | ASHLEY SANTOS |
| Website | https://www.bostonscientific.com |
| 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...

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