

K233318 AXIOS Stent and Electrocautery-Enhanced Delivery System (6mmx8mm)

Oct 27, 2023
28 days to decisionK233318 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k233318/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS) |
| Date received | Sep 29, 2023 |
| Decision date | Oct 27, 2023 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | AXIOS Stent and Electrocautery-Enhanced Delivery System (8mmx8mm); AXIOS Stent and Electrocautery-Enhanced Delivery System (10mmx10mm); AXIOS Stent and Electrocautery-Enhanced Delivery System (15mmx10mm); AXIOS Stent and Electrocautery-Enhanced Delivery System (20mmx10mm); AXIOS Stent and Electrocautery-Enhanced Delivery System (15mmx15mm) |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Corporation |
| Location | Marlborough, MA, US |
| Contact | Mr. Ian Broome |
| 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...