FDA 510(k) Premarket Notification

**CLEARED**

# K233207 Polaris X™ Unidirectional Steerable Diagnostic Catheter

Oct 27, 2023
29 days to decision

K233207 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k233207/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF) |
| Date received | Sep 28, 2023 |
| Decision date | Oct 27, 2023 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Boston Scientific Corporation** |
| Location | Marlborough, MA, US |
| Contact | Amy Reilly |
| 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...