FDA 510(k) Premarket Notification

CLEARED

K211494 Polaris X Unidirectional Steerable Diagnostic Catheter

Sep 14, 2021
124 days to decision

K211494 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k211494/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	May 13, 2021
Decision date	Sep 14, 2021
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Donall Hosna
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...