FDA 510(k) Premarket Notification

CLEARED

K192360 IntellaMap Orion High Resolution Mapping Catheter

Oct 25, 2019
56 days to decision

K192360 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k192360/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Aug 30, 2019
Decision date	Oct 25, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Nicole Lyden
Website	https://www.bostonscientific.com
510(k) history	231 submissions · 218 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...