FDA 510(k) Premarket Notification

K111043 ATLANTIS SR PRO2 CORONARY IMAGING CATHETER, ICROSS CORONARY IMAGING CATHETER

CLEARED

Aug 4, 2011
111 days to decision

K111043 · Product code: **OBJ** · Radiology
Source: https://www.510kdatabase.net/k111043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Ultrasound, Intravascular (OBJ)
Date received	Apr 15, 2011
Decision date	Aug 4, 2011
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corp**
Location	San Jose, CA, US
Contact	JANICE E BROWN, RAC
Website	https://www.bostonscientific.com/
510(k) history	432 submissions · 411 cleared · 1988-2024

Boston Scientific Corp is a global medical device manufacturer headquartered in San Jose, US. The company develops and markets devices across multiple therapeutic areas including cardiovascular, gastroenterology, and surgical specialties. Boston Scientific has maintained a strong FDA 510(k) regulatory presence since 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances in 2024 demonstrate continued innovation and active market engagement across cardiovascular and gastroenterology device categories. Recent cleared devices reflect th...