

K121667 NC QUANTUM APEX PTCA DILATATION CATHETER (MONORAIL)

Aug 13, 2012
68 days to decision

K121667 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k121667/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jun 6, 2012
Decision date	Aug 13, 2012
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corp
Location	San Jose, CA, US
Contact	LAURA J LIND
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...