FDA 510(k) Premarket Notification

K123765 GUIDEZILLA GUIDE EXTENSION CATHETER

CLEARED

Mar 19, 2013
102 days to decision

K123765 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k123765/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 7, 2012
Decision date	Mar 19, 2013
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific**
Location	San Jose, CA, US
Contact	HOLLY RAMIREZ
Website	http://www.bostonscientific.com/
510(k) history	58 submissions · 52 cleared · 2001-2026

Boston Scientific is an American biotechnology and biomedical engineering firm headquartered in Marlborough, Massachusetts. The company manufactures medical devices for interventional specialties including cardiology, endoscopy, urology, and oncology. Boston Scientific has received FDA 510(k) clearances from total submissions since 2001. The company maintains active regulatory engagement, with the latest clearance in 2025. Recent cleared devices span cardiovascular, gastroenterology, urology, orthopedic, and general surgery categories, reflecting broad therapeutic focus. ...