FDA 510(k) Premarket Notification

K060572 MODIFICATION TO POLARCATH PERIPHERAL DILATATION SYSTEM

CLEARED

Mar 15, 2006
9 days to decision

K060572 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k060572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Mar 6, 2006
Decision date	Mar 15, 2006
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	ELAINE APLAON
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...