CLEARED

Nov 4, 2016
73 days to decision

K162350 Coyote Monorail Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter, Express SD Biliary Monorail Premounted Stent System, Maverick XL Percutaneous Transluminal Coronary Angioplasty Monorail Dilatation Catheter, Sterling Monorail Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter, Ultra-Soft SV Monorail Balloon Dilatation Catheter 0.018

K162350 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k162350/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 23, 2016
Decision date	Nov 4, 2016
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Boston Scientific Corporation**
Location	Marlborough, MA, US
Contact	Ka Zoua Xiong
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...