

**K052038 PERIPHERAL CUTTING BALLOON SMALL MONORAIL
OR OVER-THE-WIRE DELIVERY SYSTEM**Aug 16, 2005
19 days to decisionK052038 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k052038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jul 28, 2005
Decision date	Aug 16, 2005
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Corporation
Location	Marlborough, MA, US
Contact	RENUKA KRISHNAN
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...

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Device record: <https://www.510kdatabase.net/k052038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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