

K062387 SMALL PERIPHERAL CUTTING BALLON, MONORAIL DELIVERY SYSTEMOct 5, 2006
51 days to decisionK062387 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k062387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Aug 15, 2006
Decision date	Oct 5, 2006
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific
Location	San Jose, CA, US
Contact	ANGIE BYLAND
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. ...

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Device record: <https://www.510kdatabase.net/k062387/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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