

K041993 2 CM PERIPHERAL CUTTING BALOONAug 16, 2004
24 days to decisionK041993 · Product code: **PNO** · Cardiovascular
Source: <https://www.510kdatabase.net/k041993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous, Cutting/scoring (PNO)
Date received	Jul 23, 2004
Decision date	Aug 16, 2004
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific lvt
Location	San Diego, CA, US
Contact	RENUKA KRISHNAN
510(k) history	2 submissions · 2 cleared · 2004-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026