

**K972512 SMASH PERCUTANEOUS TRANSLUMINAL
ANGIOPLASTY (PTA) CARDIOVASCULAR DEVICES PANEL**Feb 12, 1998
220 days to decisionK972512 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k972512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jul 7, 1997
Decision date	Feb 12, 1998
Days to decision	220 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boston Scientific Scimed, Inc.
Location	Plymouth, MN, US
Contact	RON BENNETT
510(k) history	35 submissions · 26 cleared · 1994-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972512/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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