FDA 510(k) Premarket Notification

K972512 SMASH PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CARDIOVASCULAR DEVICES PANEL

CLEARED

Feb 12, 1998
220 days to decision

K972512 · 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