FDA 510(k) Premarket Notification

K983650 BIPORE BALLOON DILATATION CATHETER

CLEARED

Feb 17, 1999
124 days to decision

K983650 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k983650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Oct 16, 1998
Decision date	Feb 17, 1999
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bipore, Inc.**
Location	Demarest, NJ, US
Contact	DURMUS KOCH
510(k) history	10 submissions · 10 cleared · 1985-2008