

K983650 BIPORE BALLOON DILATATION CATHETERFeb 17, 1999
124 days to decisionK983650 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983650/> 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 25, 2026