

**K964814 BIPORE ACCUFLEX PERCUTANEOUS SHEATH
INTRODUCER**May 7, 1997
159 days to decisionK964814 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k964814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 29, 1996
Decision date	May 7, 1997
Days to decision	159 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

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