FDA 510(k) Premarket Notification

K073434 BIPORE ACCUFLEX PERCUTANEOUS SHEATH INTRODUCER

CLEARED

Apr 1, 2008
117 days to decision

K073434 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k073434/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Dec 6, 2007
Decision date	Apr 1, 2008
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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