

**K051513 BIPORE ACCUFLEX PERCUTANEOUS SHEATH  
INTRODUCER**Dec 7, 2005  
188 days to decisionK051513 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k051513/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Introducer, Catheter (DYB)
Date received	Jun 2, 2005
Decision date	Dec 7, 2005
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051513/> 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