

**K073434 BIPORE ACCUFLEX PERCUTANEOUS SHEATH INTRODUCER**Apr 1, 2008  
117 days to decisionK073434 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k073434/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k073434/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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