

**K121822 DELICOT**Sep 10, 2012  
81 days to decisionK121822 · Product code: **HBA** · Neurology  
Source: <https://www.510kdatabase.net/k121822/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Neurosurgical Paddie (HBA)
Date received	Jun 21, 2012
Decision date	Sep 10, 2012
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>American Surgical Company, LLC</b>
Location	Lynn, MA, US
Contact	ERIK PIASIO
510(k) history	2 submissions · 2 cleared · 2012-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121822/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 8, 2026