

**K111010 SPIDERFX EMBOLIC PROTECTION DEVICE**Oct 27, 2011  
199 days to decisionK111010 · Product code: **NTE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k111010/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Apr 11, 2011
Decision date	Oct 27, 2011
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ev3, Inc.</b>
Location	Plymouth, MN, US
Contact	BRENDA JOHNSON
510(k) history	35 submissions · 26 cleared · 2003-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111010/> 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 6, 2026