

**K111987 FIBERNET EMBOLIC PROTECTION DEVICE**Aug 17, 2011  
35 days to decisionK111987 · Product code: **NTE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k111987/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Jul 13, 2011
Decision date	Aug 17, 2011
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumen Biomedical, Inc.</b>
Location	Plymouth, MN, US
Contact	MICHELLE STRAIGHT
510(k) history	5 submissions · 4 cleared · 2006-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111987/> 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 18, 2026