

**K080901 LBI EMBOLECTOMY SYSTEM**Oct 2, 2008  
185 days to decisionK080901 · Product code: **QEW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k080901/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Mar 31, 2008
Decision date	Oct 2, 2008
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lumen Biomedical, Inc.</b>
Location	Plymouth, MN, US
Contact	MARIA E BRITTLE
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/k080901/> 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