

**K222791 SafeBreak Vascular**Oct 16, 2022  
31 days to decisionK222791 · Product code: **QOI** · General Hospital  
Source: <https://www.510kdatabase.net/k222791/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intravenous Catheter Force-activated Separation Device. (QOI)
Date received	Sep 15, 2022
Decision date	Oct 16, 2022
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lineus Medical, LLC</b>
Location	Fayetteville, AZ, US
Contact	Vance Clement
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>MRC Global, LLC</b>
Contact	Dawn Norman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222791/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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