

**K223486 SafeBreak® Vascular**May 19, 2023  
179 days to decisionK223486 · Product code: **QOI** · General Hospital  
Source: <https://www.510kdatabase.net/k223486/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intravenous Catheter Force-activated Separation Device. (QOI)
Date received	Nov 21, 2022
Decision date	May 19, 2023
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lineus Medical</b>
Location	Fayetteville, AZ, US
Contact	Vance Clement
510(k) history	2 submissions · 2 cleared · 2023-2023

**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](https://accessdata.fda.gov)

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