FDA 510(k) Premarket Notification

K222791 SafeBreak Vascular

CLEARED

Oct 16, 2022
31 days to decision

K222791 · Product code: **QOI** · General Hospital
Source: https://www.510kdatabase.net/k222791/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Dawn Norman

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