FDA 510(k) Premarket Notification

K231957 SafeBreak® Vascular

CLEARED

Sep 29, 2023
88 days to decision

K231957 · Product code: **QOI** · General Hospital
Source: https://www.510kdatabase.net/k231957/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intravenous Catheter Force-activated Separation Device. (QOI)
Date received	Jul 3, 2023
Decision date	Sep 29, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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