FDA 510(k) Premarket Notification

K241415 Orchid Safety Release Valve™

CLEARED

Sep 6, 2024
112 days to decision

K241415 · Product code: **QOI** · General Hospital
Source: https://www.510kdatabase.net/k241415/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intravenous Catheter Force-activated Separation Device. (QOI)
Date received	May 17, 2024
Decision date	Sep 6, 2024
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Linear Health Sciences, LLC**
Location	Oklahoma City, OK, US
Contact	Jessica Czamanski
510(k) history	4 submissions · 4 cleared · 2022-2024