FDA 510(k) Premarket Notification

K212064 Orchid Safety Release Valve(TM)

CLEARED

May 3, 2022
305 days to decision

K212064 · Product code: **QOI** · General Hospital
Source: https://www.510kdatabase.net/k212064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intravenous Catheter Force-activated Separation Device. (QOI)
Date received	Jul 2, 2021
Decision date	May 3, 2022
Days to decision	305 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	Daniel Clark
510(k) history	4 submissions · 4 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**RQM+**
Contact	Jessica Czamanski

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