FDA 510(k) Premarket Notification

CLEARED

K230957 TriSalus TriNav® LV Infusion System

May 2, 2023
28 days to decision

K230957 · Product code: **KRA** · Cardiovascular
Source: https://www.510kdatabase.net/k230957/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Apr 4, 2023
Decision date	May 2, 2023
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Trisalus Life Sciences**
Location	Westminster, CO, US
Contact	Michael Aymami
510(k) history	3 submissions · 3 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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