

**K230957 TriSalus TriNav® LV Infusion System**May 2, 2023  
28 days to decisionK230957 · Product code: **KRA** · CardiovascularSource: <https://www.510kdatabase.net/k230957/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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