FDA 510(k) Premarket Notification

K233858 TriSalus TriGuideTM Guiding Catheter

CLEARED

Dec 27, 2023
22 days to decision

K233858 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k233858/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Dec 5, 2023
Decision date	Dec 27, 2023
Days to decision	22 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

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Device record: https://www.510kdatabase.net/k233858/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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