

K250203 SureAx-Guide™Oct 17, 2025
266 days to decisionK250203 · Product code: **DQX** · CardiovascularSource: <https://www.510kdatabase.net/k250203/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jan 24, 2025
Decision date	Oct 17, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sureax Medical, LLC
Location	San Diego, CA, US
Contact	Ricardo Villanueva
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Starlight Medical Consulting
Contact	Natalie Eagleburger

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250203/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026