

**K242597 CROSSLEAD 0.018inch**Mar 5, 2025  
187 days to decisionK242597 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k242597/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Aug 30, 2024
Decision date	Mar 5, 2025
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Asahi Intecc Co., Ltd.</b>
Location	Seto-Shi, JP
Contact	Katsuhiko Fujimura
Website	<a href="https://www.asahi-intecc.com">https://www.asahi-intecc.com</a>
510(k) history	83 submissions · 83 cleared · 2003-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Asahi Intecc USA, Inc.</b>
Contact	Cynthia Valenzuela

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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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242597/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026