

K243733 SION blue PLUSApr 2, 2025
119 days to decisionK243733 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k243733/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Dec 4, 2024
Decision date	Apr 2, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Asahi Intecc USA, Inc.
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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