

K240387 MINAMO blueJun 21, 2024
134 days to decisionK240387 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k240387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Feb 8, 2024
Decision date	Jun 21, 2024
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MINAMO viola

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Asahi Intecc USA, Inc.
Contact	C. 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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