FDA 510(k) Premarket Notification

K240387 MINAMO blue

CLEARED

Jun 21, 2024
134 days to decision

K240387 · 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