FDA 510(k) Premarket Notification

K190176 MINAMO

CLEARED

Aug 1, 2019
181 days to decision

K190176 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k190176/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Feb 1, 2019
Decision date	Aug 1, 2019
Days to decision	181 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	Yasuyuki Kawahara
Website	https://www.asahi-intecc.com
510(k) history	84 submissions · 84 cleared · 2003-2026

REGULATORY CONSULTANT

Consulting firm	**CardioMed Device Consultants, LLC**
Contact	Candace Cederman

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov