FDA 510(k) Premarket Notification

K213315 CROSSLEAD Peripheral Guide Wire

CLEARED

Jul 1, 2022
270 days to decision

K213315 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k213315/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Oct 4, 2021
Decision date	Jul 1, 2022
Days to decision	270 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	Tomoya Eguchi
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