FDA 510(k) Premarket Notification

K192782 ASAHI CROSSWALK Peripheral Support Catheter

CLEARED

Nov 29, 2019
60 days to decision

K192782 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k192782/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 30, 2019
Decision date	Nov 29, 2019
Days to decision	60 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 Kawuhara
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510(k) history	84 submissions · 84 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