FDA 510(k) Premarket Notification

K182420 ASAHI Corsair Pro XS

CLEARED

Dec 20, 2018
106 days to decision

K182420 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k182420/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 5, 2018
Decision date	Dec 20, 2018
Days to decision	106 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