

K182844 ASAHI SASUKEJun 22, 2019
256 days to decisionK182844 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k182844/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 9, 2018
Decision date	Jun 22, 2019
Days to decision	256 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](https://accessdata.fda.gov)

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