FDA 510(k) Premarket Notification

K241158 ASAHI Veloute

CLEARED

Jun 25, 2024
60 days to decision

K241158 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k241158/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 26, 2024
Decision date	Jun 25, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ASAHI Veloute C3; ASAHI Tellus; ASAHI Tellus C3

APPLICANT

Company	**Asahi Intecc Co., Ltd.**
Location	Seto-Shi, JP
Contact	Fujimura Katsuhiko
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