

**K241158 ASAHI Veloute**Jun 25, 2024  
60 days to decisionK241158 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k241158/>**SUBMISSION DETAILS**

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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**

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Company	<b>Asahi Intecc Co., Ltd.</b>
Location	Seto-Shi, JP
Contact	Fujimura Katsuhiko
Website	<a href="https://www.asahi-intecc.com">https://www.asahi-intecc.com</a>
510(k) history	83 submissions · 83 cleared · 2003-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Asahi Intecc USA, Inc.</b>
Contact	Cynthia Valenzuela

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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