

K152447 ASAHI CaravelJan 22, 2016
148 days to decisionK152447 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k152447/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 27, 2015
Decision date	Jan 22, 2016
Days to decision	148 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Asahi Intecc Co., Ltd.
Location	Seto-Shi, JP
Contact	YOSHIHIKO FUKUI
Website	https://www.asahi-intecc.com
510(k) history	83 submissions · 83 cleared · 2003-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026