

K182035 FFRctDec 6, 2018
129 days to decisionK182035 · Product code: **PJA** · Cardiovascular
Source: <https://www.510kdatabase.net/k182035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coronary Vascular Physiologic Simulation Software (PJA)
Date received	Jul 30, 2018
Decision date	Dec 6, 2018
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	HeartFlow, Inc.
Location	Redwood City, CA, US
Contact	Windi Hary
510(k) history	7 submissions · 7 cleared · 2016-2025

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