

K161772 FFRctAug 24, 2016
57 days to decisionK161772 · Product code: **PJA** · Cardiovascular
Source: <https://www.510kdatabase.net/k161772/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coronary Vascular Physiologic Simulation Software (PJA)
Date received	Jun 28, 2016
Decision date	Aug 24, 2016
Days to decision	57 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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