

K213857 HeartFlow AnalysisOct 14, 2022
308 days to decisionK213857 · Product code: **PJA** · Cardiovascular
Source: <https://www.510kdatabase.net/k213857/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coronary Vascular Physiologic Simulation Software (PJA)
Date received	Dec 10, 2021
Decision date	Oct 14, 2022
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	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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