

K250902 HeartFlow AnalysisJul 18, 2025
114 days to decisionK250902 · Product code: **PJA** · Radiology
Source: <https://www.510kdatabase.net/k250902/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coronary Vascular Physiologic Simulation Software (PJA)
Date received	Mar 26, 2025
Decision date	Jul 18, 2025
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250902/> 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 May 13, 2026