FDA 510(k) Premarket Notification

K250902 HeartFlow Analysis

CLEARED

Jul 18, 2025
114 days to decision

K250902 · 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