

K190925 HeartFlow FFRct AnalysisAug 15, 2019
128 days to decisionK190925 · Product code: **PJA** · Cardiovascular
Source: <https://www.510kdatabase.net/k190925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coronary Vascular Physiologic Simulation Software (PJA)
Date received	Apr 9, 2019
Decision date	Aug 15, 2019
Days to decision	128 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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