

**K213657 DEEPVESSEL FFR**Apr 1, 2022  
133 days to decisionK213657 · Product code: **PJA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k213657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coronary Vascular Physiologic Simulation Software (PJA)
Date received	Nov 19, 2021
Decision date	Apr 1, 2022
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Keyamed Na, Inc.</b>
Location	Seattle, WA, US
Contact	Xiaoxiao Liu
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Kelliann Payne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

**CLINICAL EVIDENCE - NCT04828590****The ADAPT Study: Assessment of the DiAgnostic Performance of DeepVessel FFR in SuspecTed Coronary Artery Disease**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	302 patients (actual)
Study sites	10 sites
Condition studied	Coronary Artery Disease; Myocardial Ischemia
Study type	Observational
Completion date	Dec 31, 2021
Sponsor	Keya Medical (Industry)

**Primary outcome**Sensitivity of DVFFR at the vessel level in identifying ischemic lesions, i.e. DVFFR value  $\geq 0.80$ , from coronary CTA images, using ICA-FFR measurement as a reference standard.**Secondary outcome**

Diagnostic accuracy, positive predictive value (PPV) and negative predictive value (NPV) of DVFFR at the vessel level

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04828590](https://clinicaltrials.gov/study/NCT04828590)