FDA 510(k) Premarket Notification

K182149 FFRangio System

CLEARED

Dec 19, 2018
133 days to decision

K182149 · Product code: **QEK** · Cardiovascular
Source: https://www.510kdatabase.net/k182149/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Angiographic Coronary Vascular Physiologic Simulation Software (QEK)
Date received	Aug 8, 2018
Decision date	Dec 19, 2018
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cathworks, Ltd.**
Location	Kfar-Saba, IL
Contact	Miriam Ivenshitz
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	**Heyer Regulatory Solutions, LLC**
Contact	Sheila Hemeon-Heyer

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

CLINICAL EVIDENCE - NCT03226262

FFRangio Accuracy vs. Standard FFR

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	382 patients (actual)
Study sites	9 sites
Condition studied	Coronary Artery Disease
Study type	Observational
Completion date	Jun 8, 2018
Sponsor	CathWorks Ltd. (Industry)

Primary outcome

Sensitivity and specificity of the dichotomously scored FFRangio measured index compared to invasive FFR

Secondary outcome

Continuously scored FFR (FFRangio and Invasive FFR).

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03226262