FDA 510(k) Premarket Notification

K192442 FFRangio

CLEARED

Dec 9, 2019
94 days to decision

K192442 · Product code: **QEK** · Cardiovascular
Source: https://www.510kdatabase.net/k192442/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Angiographic Coronary Vascular Physiologic Simulation Software (QEK)
Date received	Sep 6, 2019
Decision date	Dec 9, 2019
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cathworks, Ltd.**
Location	Kfar-Saba, IL
Contact	Asaf Azulay
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