FDA 510(k) Premarket Notification

K211611 QIR Suite

CLEARED

Sep 30, 2022
493 days to decision

K211611 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k211611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 25, 2021
Decision date	Sep 30, 2022
Days to decision	493 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Casis Cardiac Simulation & Imaging Software**
Location	Quetigny, FR
Contact	Jean-Joseph Christophe
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Gloster Biomedical International**
Contact	Catherine Gloster

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