FDA 510(k) Premarket Notification

K201250 SQuEEZ Software

CLEARED

Dec 18, 2020
221 days to decision

K201250 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k201250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 11, 2020
Decision date	Dec 18, 2020
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiowise, Inc.**
Location	Fayetteville, AR, US
Contact	John Coats
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Acknowledge Regulatory Strategies, LLC**
Contact	Pierre Bounaud

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