FDA 510(k) Premarket Notification

K211656 3D Echo v1.1

CLEARED

Jun 25, 2021
28 days to decision

K211656 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k211656/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 28, 2021
Decision date	Jun 25, 2021
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jointvue, LLC**
Location	Knoxville, TN, US
Contact	Maja Ward
510(k) history	3 submissions · 3 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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