FDA 510(k) Premarket Notification

K201365 True 3D Viewer

CLEARED

Jul 17, 2020
56 days to decision

K201365 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k201365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 22, 2020
Decision date	Jul 17, 2020
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Echopixel, Inc.**
Location	Mountain View, CA, US
Contact	Michael Gabler
510(k) history	4 submissions · 4 cleared · 2015-2020

REGULATORY CONSULTANT

Consulting firm	**Sheila Pickering Consulting Group**
Contact	Sheila Pickering

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