

K193149 True 3D Viewer SoftwareDec 27, 2019
44 days to decisionK193149 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k193149/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Nov 13, 2019
Decision date	Dec 27, 2019
Days to decision	44 days
Third-party review	Yes
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	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193149/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026