

K211791 Ez3D-i/E3Aug 20, 2021
71 days to decisionK211791 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k211791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 10, 2021
Decision date	Aug 20, 2021
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ewoosoft Co., Ltd.
Location	Houston, TX, US
Contact	Young Seok Kim
510(k) history	31 submissions · 31 cleared · 2013-2025

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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