

K190791 Ez3D-i/E3Apr 19, 2019
23 days to decisionK190791 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k190791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Mar 27, 2019
Decision date	Apr 19, 2019
Days to decision	23 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

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