

K231757 Ez3D-i /E3Jul 14, 2023
28 days to decisionK231757 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k231757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jun 16, 2023
Decision date	Jul 14, 2023
Days to decision	28 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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