FDA 510(k) Premarket Notification

# K211791 Ez3D-i/E3

**CLEARED**

Aug 20, 2021
71 days to decision

K211791 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k211791/

## SUBMISSION DETAILS

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|---|---|
| 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

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|---|---|
| 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