FDA 510(k) Premarket Notification

K220003 EzOrtho v1.3

CLEARED

Feb 23, 2022
50 days to decision

K220003 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k220003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 4, 2022
Decision date	Feb 23, 2022
Days to decision	50 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