

**K220003 EzOrtho v1.3**Feb 23, 2022  
50 days to decisionK220003 · 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	<b>Ewoosoft Co., Ltd.</b>
Location	Houston, TX, US
Contact	Young Seok Kim
510(k) history	31 submissions · 31 cleared · 2013-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>LK Consulting Group USA, Inc.</b>
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)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220003/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026