

K213891 RealNowFeb 24, 2023
437 days to decisionK213891 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k213891/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 14, 2021
Decision date	Feb 24, 2023
Days to decision	437 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Yiwei Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Eric Ke
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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