FDA 510(k) Premarket Notification

K213891 RealNow

CLEARED

Feb 24, 2023
437 days to decision

K213891 · 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