FDA 510(k) Premarket Notification

K240371 0909FCC, 0909FCC-HS

CLEARED

Mar 7, 2024
29 days to decision

K240371 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k240371/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Feb 7, 2024
Decision date	Mar 7, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rayence Co., Ltd.**
Location	Houston, TX, US
Contact	Inhwan Bang
510(k) history	38 submissions · 38 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	**Mtech Group, LLC**
Contact	Dave Kim

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