

**K240371 0909FCC, 0909FCC-HS**Mar 7, 2024  
29 days to decisionK240371 · 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	<b>Rayence Co., Ltd.</b>
Location	Houston, TX, US
Contact	Inhwan Bang
510(k) history	38 submissions · 38 cleared · 2011-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Mtech Group, LLC</b>
Contact	Dave Kim

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/k240371/> 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