

K212753 0909FCB, 1212FCAOct 18, 2021
48 days to decisionK212753 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k212753/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Aug 31, 2021
Decision date	Oct 18, 2021
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
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)

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