FDA 510(k) Premarket Notification

K253800 0909FCE, 0909FCE-HS

CLEARED

Jul 31, 2026
245 days to decision

K253800 · Product code: **MQB** · Radiology
Source: https://www.510kdatabase.net/k253800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	Nov 28, 2025
Decision date	Jul 31, 2026
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rayence Co., Ltd.**
Location	Houston, TX, US
Contact	Sung Woo Jung
510(k) history	39 submissions · 39 cleared · 2011-2026

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