

**K231467 1417WCE, 1417WCE-HR, 1417WCE-HS, 1417WCE-GF**Jun 21, 2023  
30 days to decisionK231467 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k231467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 22, 2023
Decision date	Jun 21, 2023
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtechgroup</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)

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