

K242394 Digital Flat Panel X-ray Detector (1717WCE, 1717WCE-HR, 1717WCE-HS, 1717WCE-GF)Sep 9, 2024
27 days to decisionK242394 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k242394/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Aug 13, 2024 |
| Decision date | Sep 9, 2024 |
| Days to decision | 27 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

REGULATORY CONSULTANT

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|-----------------|-------------------------|
| 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242394/>; Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026