

K243849 2430TCA with Xmaru WMar 12, 2025
86 days to decisionK243849 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k243849/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Full Field Digital, System, X-ray, Mammographic (MUE) |
| Date received | Dec 16, 2024 |
| Decision date | Mar 12, 2025 |
| Days to decision | 86 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

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](https://accessdata.fda.gov)

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