

**K202902 2430MCA with Xmaru W**Jun 21, 2021  
265 days to decisionK202902 · Product code: **MUE** · Radiology  
Source: <https://www.510kdatabase.net/k202902/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Sep 29, 2020
Decision date	Jun 21, 2021
Days to decision	265 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	Kee Dock 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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202902/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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