FDA 510(k) Premarket Notification

K202902 2430MCA with Xmaru W

CLEARED

Jun 21, 2021
265 days to decision

K202902 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k202902/

SUBMISSION DETAILS

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

Company	**Rayence Co., Ltd.**
Location	Houston, TX, US
Contact	Kee Dock Kim
510(k) history	38 submissions · 38 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	**Mtechgroup**
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov