FDA 510(k) Premarket Notification

K213462 EzRay M18 (Model: VMX-P400)

CLEARED

Feb 11, 2022
107 days to decision

K213462 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k213462/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Oct 27, 2021
Decision date	Feb 11, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**VATECH Co., Ltd.**
Location	Sound Beach, NY, US
Contact	Daniel Kim
510(k) history	39 submissions · 39 cleared · 2008-2025

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k213462/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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