FDA 510(k) Premarket Notification

# K203667 EzRay M (Model: VMX-P300)

**CLEARED**

Feb 2, 2021
48 days to decision

K203667 · Product code: **IZL** · Radiology
Source: https://www.510kdatabase.net/k203667/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, X-ray, Mobile (IZL) |
| Date received | Dec 16, 2020 |
| Decision date | Feb 2, 2021 |
| Days to decision | 48 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