

K223058 EzRay Air 2 Wall (Model: VEX-S350W)Oct 26, 2022
26 days to decisionK223058 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k223058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Sep 30, 2022
Decision date	Oct 26, 2022
Days to decision	26 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](https://accessdata.fda.gov)

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