

K161063 EzRay Air (Model VEX-P300)Sep 1, 2016
139 days to decisionK161063 · Product code: **EHD** · Radiology
Source: <https://www.510kdatabase.net/k161063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Apr 15, 2016
Decision date	Sep 1, 2016
Days to decision	139 days
Third-party review	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

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