FDA 510(k) Premarket Notification

CLEARED

K200182 EzRay Air Portable (Model: VEX-P300)

Feb 11, 2020
18 days to decision

K200182 · Product code: **EHD** · Radiology
Source: https://www.510kdatabase.net/k200182/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jan 24, 2020
Decision date	Feb 11, 2020
Days to decision	18 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k200182/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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