

**K243081 Green X 21 (PHT-90CHO)**Feb 14, 2025  
137 days to decisionK243081 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k243081/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Sep 30, 2024
Decision date	Feb 14, 2025
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtech Group, LLC</b>
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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