

K243088 Green X 12 SE (PHT-40CHS)Feb 21, 2025
144 days to decisionK243088 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k243088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Sep 30, 2024
Decision date	Feb 21, 2025
Days to decision	144 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 Lim
510(k) history	39 submissions · 39 cleared · 2008-2025

REGULATORY CONSULTANT

Consulting firm	Mtech Group, LLC
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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