

K210329 Green X 18(Model : PHT-75CHS)Feb 18, 2021
14 days to decisionK210329 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k210329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 4, 2021
Decision date	Feb 18, 2021
Days to decision	14 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

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