

K160882 PaX-i3D Green Premium (Model: PCT-90LH)Oct 28, 2016
211 days to decisionK160882 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k160882/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Mar 31, 2016
Decision date	Oct 28, 2016
Days to decision	211 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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