

**K121400 PAX-UNI3D, PHT-7500**Aug 28, 2012  
110 days to decisionK121400 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k121400/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	May 10, 2012
Decision date	Aug 28, 2012
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121400/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 17, 2026