

K132983 TON-95LH, PAX-I3D ORTHOAug 7, 2014
318 days to decisionK132983 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k132983/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Sep 23, 2013
Decision date	Aug 7, 2014
Days to decision	318 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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