

K150354 PAPAYA 3D PlusDec 10, 2015
302 days to decisionK150354 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k150354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 11, 2015
Decision date	Dec 10, 2015
Days to decision	302 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genoray Co., Ltd.
Location	Flintville, TN, US
Contact	Kyoung-hwa Kim
510(k) history	24 submissions · 24 cleared · 2007-2026

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