

K220392 PAPAYA 3D & PAPAYA 3D PlusMay 19, 2022
97 days to decisionK220392 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k220392/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 11, 2022
Decision date	May 19, 2022
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Genoray America, Inc.
Contact	Kaitlynn Min

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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