

**K200469 PAPAYA 3D Premium & PAPAYA 3D Premium Plus**Sep 16, 2020  
203 days to decisionK200469 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k200469/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 26, 2020
Decision date	Sep 16, 2020
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genoray Co., Ltd.</b>
Location	Flintville, TN, US
Contact	Hyunju Hwang
510(k) history	24 submissions · 24 cleared · 2007-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200469/> 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 14, 2026