

K250060 GT300Oct 8, 2025
271 days to decisionK250060 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k250060/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jan 10, 2025
Decision date	Oct 8, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GT300-C

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Genoray America, Inc.
Contact	Suyoung Jo

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

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