

**K250692 GentleBeam (GB1000)**Dec 3, 2025  
271 days to decisionK250692 · Product code: **JAD** · Radiology  
Source: <https://www.510kdatabase.net/k250692/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Therapeutic, X-ray (JAD)
Date received	Mar 7, 2025
Decision date	Dec 3, 2025
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Voxel Ray Solutions, LLC</b>
Location	Burr Ridge, IL, US
Contact	Nicolas Soro
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250692/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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