

**K250392 ZAP-X Radiosurgery System (ZAP-X)**Nov 3, 2025  
264 days to decisionK250392 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k250392/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Feb 12, 2025
Decision date	Nov 3, 2025
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zap Surgical Systems, Inc.</b>
Location	San Carlos, CA, US
Contact	Junyi Wang
510(k) history	2 submissions · 2 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250392/> 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 13, 2026