

**K183698 Zap-X Radiosurgery System**Feb 25, 2019  
56 days to decisionK183698 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k183698/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 31, 2018
Decision date	Feb 25, 2019
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zap Surgical Systems</b>
Location	San Carlos, CA, US
Contact	Jim Talbot
510(k) history	2 submissions · 2 cleared · 2017-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183698/> 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 June 28, 2026