

**K212101 da Vinci SP Firefly Imaging System**Nov 23, 2021  
140 days to decisionK212101 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212101/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Surgical, Computer Controlled Instrument (NAY)
Date received	Jul 6, 2021
Decision date	Nov 23, 2021
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intuitive Surgical, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Connor McCarty
Website	<a href="https://www.intuitive.com">https://www.intuitive.com</a>
510(k) history	176 submissions · 156 cleared · 1997-2026

Intuitive Surgical, Inc. is an American biotechnology company headquartered in Sunnyvale that develops and manufactures robotic surgical systems. The company specializes in minimally invasive surgery technologies, most notably the da Vinci Surgical System. Intuitive Surgical has received FDA 510(k) clearances from total submissions since its first clearance in 1997. The company's dominant focus is General & Plastic Surgery devices, which represent 87% of its regulatory submissions. The latest FDA 510(k) clearance was granted in 2026, reflecting continued innovation and ac...

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Device record: <https://www.510kdatabase.net/k212101/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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