

K252350 da Vinci SP Firefly Imaging SystemAug 28, 2025
30 days to decisionK252350 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k252350/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, Surgical, Computer Controlled Instrument (NAY) |
| Date received | Jul 29, 2025 |
| Decision date | Aug 28, 2025 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Intuitive Surgical, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | Connor McCarty |
| Website | https://www.intuitive.com |
| 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/k252350/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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