

**K124031 DA VINCI FLUORESCENCE IMAGING VISION SYSTEM**Sep 13, 2013  
259 days to decisionK124031 · Product code: **OWN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k124031/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Confocal Optical Imaging (OWN)     |
| Date received         | Dec 28, 2012                       |
| Decision date         | Sep 13, 2013                       |
| Days to decision      | 259 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Intuitive Surgical, Inc.</b>                                   |
| Location       | Sunnyvale, CA, US   |
| Contact        | CINDY DOMECUS   |
| 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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