

**K001666 MODIFICATION TO INTUITIVE SURGICAL STEREO VIEW ENDOSCOPIC SYSTEM**Aug 24, 2000  
85 days to decisionK001666 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k001666/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received         | May 31, 2000                                 |
| Decision date         | Aug 24, 2000                                 |
| Days to decision      | 85 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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