

K081207 INTUITIVE SURGICAL DA VINCI S SURGICAL SYSTEM, MODEL IS2000, WITH DA VINCI CONNECT AND ONSITEDec 19, 2008
234 days to decisionK081207 · Product code: **NAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k081207/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Surgical, Computer Controlled Instrument (NAY) |
| Date received | Apr 29, 2008 |
| Decision date | Dec 19, 2008 |
| Days to decision | 234 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Intuitive Surgical, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | JERRY TSUTSUMI |
| 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...