

K080155 MODIFICATION TO:INTUITIVE SURGICAL STEREO VIEW ENDOSCOPIC SYSTEMMar 6, 2008
43 days to decisionK080155 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k080155/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | Jan 23, 2008 |
| Decision date | Mar 6, 2008 |
| Days to decision | 43 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Intuitive Surgical, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | MICHAEL H YRAMATEGUI |
| 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/k080155/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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