

K170645 da Vinci Xi EndoWrist Instruments and AccessoriesSep 11, 2017
193 days to decisionK170645 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k170645/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Surgical, Computer Controlled Instrument (NAY) |
| Date received | Mar 2, 2017 |
| Decision date | Sep 11, 2017 |
| Days to decision | 193 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Intuitive Surgical, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | Kunal Gunjal |
| 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...
