

K211997 8 mm SureForm 30 Curved-Tip Stapler, 8 mm SureForm 30 Stapler, SureForm 30 ReloadsDec 10, 2021
165 days to decisionK211997 · Product code: **NAY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211997/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Surgical, Computer Controlled Instrument (NAY) |
| Date received | Jun 28, 2021 |
| Decision date | Dec 10, 2021 |
| Days to decision | 165 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Intuitive Surgical, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | Amrit Jaggi |
| 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...