

K181395 Universal Cannula Seal (5-12 mm)Jul 27, 2018
59 days to decisionK181395 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k181395/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | May 29, 2018 |
| Decision date | Jul 27, 2018 |
| Days to decision | 59 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Intuitive Surgical, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | Cheryl Wu |
| 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...
