

K212055 Connected OR Hub with Device and Voice ControlDec 16, 2021
168 days to decisionK212055 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k212055/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received | Jul 1, 2021 |
| Decision date | Dec 16, 2021 |
| Days to decision | 168 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Stryker Corporation |
| Location | Malwah, NJ, US |
| Contact | Eugene Perelshteyn |
| Website | http://www.stryker.com/ |
| 510(k) history | 81 submissions · 81 cleared · 2010-2023 |

Stryker Corporation is an American multinational medical technology company headquartered in Portage, Michigan. The company develops and markets surgical equipment, neurotechnology, orthopedic implants, and patient safety systems used globally across medical specialties. Stryker has received FDA 510(k) clearances from total submissions between 2010 and 2023. The company's cleared devices span orthopedic surgery, neurosurgery, general and plastic surgery, and ear, nose, and throat specialties. This regulatory record reflects the company's broad portfolio across surgical an...