

K220665 Surgical Gown, Blue, SterileJun 3, 2022
88 days to decisionK220665 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k220665/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Surgical (FYA) |
| Date received | Mar 7, 2022 |
| Decision date | Jun 3, 2022 |
| Days to decision | 88 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |
| Other names | Surgical Gown, Blue, Non-Sterile |

APPLICANT

| | |
|----------------|---|
| Company | Excellent Medical Technology Group Co., Ltd. |
| Location | Suzhou, CN |
| Contact | Kenney Song |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Guangzhou Osmunda Medical Device Technical Service Co., Ltd. |
| Contact | Olivia Meng |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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