

K222403 Surgical GownJan 26, 2023
170 days to decisionK222403 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k222403/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Surgical (FYA) |
| Date received | Aug 9, 2022 |
| Decision date | Jan 26, 2023 |
| Days to decision | 170 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Guangzhou Fuzelong Hygiene Material Co., Ltd. |
| Location | Guangzhou, CN |
| Contact | Yuehua Zhou |
| 510(k) history | 2 submissions · 2 cleared · 2023-2023 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai Truthful Information Technology Co., Ltd. |
| Contact | Boyle Wang |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222403/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026