

K210215 Surgical GownsJul 7, 2021
161 days to decisionK210215 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k210215/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Surgical (FYA) |
| Date received | Jan 27, 2021 |
| Decision date | Jul 7, 2021 |
| Days to decision | 161 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Jiangsu Province Jianerkang Medical Dressing Co., Ltd. |
| Location | Changzhou, CN |
| Contact | Tang Hongfang |
| 510(k) history | 2 submissions · 2 cleared · 2020-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210215/> 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