

K212422 Disposable Surgical Isolation GownApr 29, 2022
268 days to decisionK212422 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k212422/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Gown, Isolation, Surgical (FYC) |
| Date received | Aug 4, 2021 |
| Decision date | Apr 29, 2022 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Crown Name Disposable Hygiene Products Fty., Ltd. |
| Location | Wuhan, CN |
| Contact | Ying Fang |
| 510(k) history | 2 submissions · 2 cleared · 2021-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai Jiushun Enterprise Management Technology Service Co |
| Contact | Doris Chen |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212422/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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