FDA 510(k) Premarket Notification

# K221272 Medical Face Mask

**CLEARED**

Jun 28, 2022
57 days to decision

K221272 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k221272/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | May 2, 2022 |
| Decision date | Jun 28, 2022 |
| Days to decision | 57 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Shandong Xingyu Gloves Co., Ltd.** |
| Location | Gaomi, CN |
| Contact | Carrie Li |
| 510(k) history | 4 submissions · 4 cleared · 2017-2024 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Shanghai Sungo Management Consulting Company Limited.** |
| Contact | Jarvis Wu |

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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k221272/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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