

K211454 Surgical maskAug 18, 2021
100 days to decisionK211454 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211454/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | May 10, 2021 |
| Decision date | Aug 18, 2021 |
| Days to decision | 100 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Jiangsu Xingtong Biotechnology Group Co., Ltd. |
| Location | Yangzhou, CN |
| Contact | Li Hua |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

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|-----------------|--|
| Consulting firm | Shenzhen Joyantech Consulting Co., Ltd. |
| Contact | James Tsai |

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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