

K210042 Disposable Surgical MaskNov 17, 2021
314 days to decisionK210042 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210042/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mask, Surgical (FXX) |
| Date received | Jan 7, 2021 |
| Decision date | Nov 17, 2021 |
| Days to decision | 314 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Suzhou Letian Protective Products Co., Ltd. |
| Location | Suzhou, CN |
| Contact | Huang Qizhi |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai Mind-Link Business Consulting Co., Ltd. |
| Contact | Ryan Li |

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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