

K210244 Disposable Medical Face MaskJul 12, 2021
164 days to decisionK210244 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 29, 2021
Decision date	Jul 12, 2021
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Bolisi Medical Technology Co., Ltd.
Location	Zhangjiagang, CN
Contact	Hong Xu
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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