

K210023 Surgical Face MaskApr 2, 2021
88 days to decisionK210023 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 4, 2021
Decision date	Apr 2, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Winsun Personal Care Products Co.,Ltd
Location	Foshan, CN
Contact	Dong Pingping
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Grace Liu

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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