

K203646 Disposable Medical Face MaskApr 22, 2021
129 days to decisionK203646 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 14, 2020
Decision date	Apr 22, 2021
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Mei Yi Kang Medical Technology Co., Ltd.
Location	Guangzhou, CN
Contact	Lou Yonghui
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203646/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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