

K202107 Medical Protective MaskJan 15, 2021
170 days to decisionK202107 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 29, 2020
Decision date	Jan 15, 2021
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Kingfa Sci. & Tech.Co., Ltd.
Location	Qingyuan, CN
Contact	Yu Xiaoge
510(k) history	14 submissions · 14 cleared · 2020-2024

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

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