

K213450 Medical surgical mask (Black mask, Level 1 and Level 3)Apr 5, 2022
161 days to decisionK213450 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k213450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 26, 2021
Decision date	Apr 5, 2022
Days to decision	161 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

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