

K223686 Medical Protective MasksFeb 7, 2023
60 days to decisionK223686 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k223686/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 9, 2022
Decision date	Feb 7, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qinhuangdao Taizhi Medical Technology Co., Ltd.
Location	Qinhuangdao, CN
Contact	Fan Xifan
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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