

K223232 Procedure mask/Surgical mask/Face maskMar 6, 2023
138 days to decisionK223232 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k223232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 19, 2022
Decision date	Mar 6, 2023
Days to decision	138 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Winner Medical Co., Ltd.
Location	Shenzhen, CN
Contact	Mingni Liu
510(k) history	18 submissions · 18 cleared · 2019-2025

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