

K250082 Procedure mask/Surgical mask/Face maskJun 18, 2025
156 days to decisionK250082 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k250082/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 13, 2025
Decision date	Jun 18, 2025
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250082/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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