

K221038 Disposable Medical MasksSep 1, 2022
147 days to decisionK221038 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k221038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 7, 2022
Decision date	Sep 1, 2022
Days to decision	147 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hantech Medical Device Co., Ltd.
Location	Ningbo, CN
Contact	Arnold Yang
510(k) history	5 submissions · 5 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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