

K202905 Disposable Face MaskMar 26, 2021
178 days to decisionK202905 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 29, 2020
Decision date	Mar 26, 2021
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Excellence Medical Supplies Co., Ltd.
Location	Changzhou, CN
Contact	Jing Zhu
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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/k202905/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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