

K202605 Standard Procedure Mask, Standard Surgical MaskFeb 10, 2021
155 days to decisionK202605 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 8, 2020
Decision date	Feb 10, 2021
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Medplus Non-Woven Manufacturer Co., Ltd.
Location	Siyang, CN
Contact	Shuying An
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/k202605/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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