

K202341 Disposable Surgical MaskFeb 12, 2021
179 days to decisionK202341 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 17, 2020
Decision date	Feb 12, 2021
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Jianzhong Medical Packaging Co., Ltd.
Location	Shanghai, CN
Contact	Nina Huang
510(k) history	3 submissions · 3 cleared · 2007-2025

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](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202341/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026