

K203112 Disposable Medical MaskSep 16, 2021
336 days to decisionK203112 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 15, 2020
Decision date	Sep 16, 2021
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Yangzhou Runyi Arts & Crafts Co., Ltd.
Location	Yangzhou, CN
Contact	Li Yu
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Wenzhou Cytech Information Service Co., Ltd.
Contact	Helen Nan

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/k203112/> 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 26, 2026