

K202191 Surgical MaskMar 29, 2021
236 days to decisionK202191 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 5, 2020
Decision date	Mar 29, 2021
Days to decision	236 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Zonsen Medical Products Co., Ltd.
Location	Wuhan, CN
Contact	Shirly Xi
510(k) history	6 submissions · 6 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

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/k202191/> 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 24, 2026