

K220191 Disposable Face MaskMay 24, 2022
120 days to decisionK220191 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k220191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 24, 2022
Decision date	May 24, 2022
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiujiang Taixin Technology Co., Ltd.
Location	Ruichang City, CN
Contact	Li Xiaojie
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

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/k220191/> 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