

K222266 Surgical Mask (GFM 96, GFM 91, GFM 90, GFM 88, GFM 81, GFM 80)Sep 26, 2022
60 days to decisionK222266 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k222266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 28, 2022
Decision date	Sep 26, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jingzhou Haixin Green Cross Medical Products Co., Ltd.
Location	Wuhan, CN
Contact	Lei Da
510(k) history	2 submissions · 2 cleared · 2018-2022

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/k222266/> 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 25, 2026