

K202358 Protective Face Mask for Medical UseJan 29, 2021
163 days to decisionK202358 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 19, 2020
Decision date	Jan 29, 2021
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Heng Chang Pharmaceutical Co., Ltd.
Location	Changsha, CN
Contact	Tao Jingfeng
510(k) history	2 submissions · 2 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Landlink Medical Information Technology Co., Ltd.
Contact	Shelley Li

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/k202358/> 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