

K202627 Medical Face MasksFeb 3, 2021
145 days to decisionK202627 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 11, 2020
Decision date	Feb 3, 2021
Days to decision	145 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guilin Hbm Sanitary Protections, Inc.
Location	Guilin, CN
Contact	Liu Xin
510(k) history	1 submissions · 1 cleared · 2021-2021

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)

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