

K202493 Medical Face MaskFeb 4, 2021
157 days to decisionK202493 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202493/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 31, 2020
Decision date	Feb 4, 2021
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gentier Medical (Shanghai), Inc.
Location	Shanghai, CN
Contact	Li Zhiqing
510(k) history	5 submissions · 5 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Medical Business Consulting Co., Ltd.
Contact	Julie Chen

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/k202493/> 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