

K222204 Medical Surgical MaskSep 23, 2022
60 days to decisionK222204 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k222204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 25, 2022
Decision date	Sep 23, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangzhou Zhengkang Medical Equipment Co.,Ltd
Location	Guangzhou, CN
Contact	Mike Wu
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Feiyang Drug & Medical Consulting Technical Service Group
Contact	Riley 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/k222204/> 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