

K210679 Medical Face MaskJan 18, 2022
316 days to decisionK210679 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k210679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 8, 2021
Decision date	Jan 18, 2022
Days to decision	316 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wuxi Yushou Medical Appliances Co., Ltd.
Location	Wuxi, CN
Contact	Xiaoling Dai
510(k) history	2 submissions · 2 cleared · 2016-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210679/> 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