

K202843 Surgical Face Masks (Sterile), Surgical Face Masks (Non-sterile)Jan 12, 2021
109 days to decisionK202843 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k202843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 25, 2020
Decision date	Jan 12, 2021
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., Ltd.
Location	Beijing, CN
Contact	Jiahui Li
510(k) history	5 submissions · 5 cleared · 2011-2021

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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/k202843/> 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