

K231719 Medical Surgical MaskMar 19, 2024
280 days to decisionK231719 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k231719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 13, 2023
Decision date	Mar 19, 2024
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Azur Medical Company, Inc.
Location	Richmond, VA, US
Contact	Di Zhao
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai Lingfu Technology Co., Ltd.
Contact	Esther Zhang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231719/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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