

K220824 Medical Surgical Mask (Planar type)May 19, 2022
59 days to decisionK220824 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k220824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 21, 2022
Decision date	May 19, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Chopard Medical Devices Co., Ltd.
Location	Liuyang, CN
Contact	Hongwei Wei
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

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

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