

K213358 Surgical MaskMar 4, 2022
143 days to decisionK213358 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k213358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 12, 2021
Decision date	Mar 4, 2022
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Safesecure Medical Infection Control Tech Co. , Ltd.
Location	Shenzhen, CN
Contact	Patty Chen
510(k) history	3 submissions · 3 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Eva Li

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

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