

K213617 Surgical Face MaskFeb 11, 2022
88 days to decisionK213617 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k213617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 15, 2021
Decision date	Feb 11, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megasoft (China) Co., Ltd.
Location	Shishi, CN
Contact	Sarah Qiu
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213617/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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