

K202903 Surgical Face MaskMar 24, 2022
541 days to decisionK202903 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 29, 2020
Decision date	Mar 24, 2022
Days to decision	541 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rizhao Sanqi Medical & Health Articles Co., Ltd.
Location	Rizhao, CN
Contact	Julia Yu
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
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/k202903/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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