

K212368 Surgical Face MaskOct 24, 2021
86 days to decisionK212368 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 30, 2021
Decision date	Oct 24, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Tiankang Medical Technology Co., Ltd.
Location	Tianchang, CN
Contact	Zhang Yong
510(k) history	12 submissions · 12 cleared · 2019-2023

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](https://accessdata.fda.gov)

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