

K211631 Surgical Face MaskAug 18, 2021
83 days to decisionK211631 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 27, 2021
Decision date	Aug 18, 2021
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Macheng Thimble Technology Investment Co., Ltd.
Location	Huanggang, CN
Contact	Donghong Sheng
510(k) history	1 submissions · 1 cleared · 2021-2021

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/k211631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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