

K211552 Surgical maskAug 11, 2021
84 days to decisionK211552 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 19, 2021
Decision date	Aug 11, 2021
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Shengquan New Materials Co., Ltd.
Location	Jinan, CN
Contact	Xiumei Zhang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Qisheng Business Consulting Co., Ltd.
Contact	Daniel Qiu

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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