

K201625 Disposable Medical Surgical MaskJan 12, 2021
211 days to decisionK201625 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Jun 15, 2020
Decision date	Jan 12, 2021
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tianjin Saiyuan Technology Co., Ltd.
Location	Tianjin, CN
Contact	Hong Cai
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Andon Health Co, Ltd.
Contact	Wang Yanhong

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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