

K202323 Disposable Medical Surgical MasksFeb 2, 2021
169 days to decisionK202323 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 17, 2020
Decision date	Feb 2, 2021
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tianjin Teda Jinshan Easy Packing Manufacture Co., Ltd.
Location	Tianjin, CN
Contact	Hui Liu
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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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