

K202594 Medical Surgical Masks-Non SterileJan 6, 2021
120 days to decisionK202594 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 8, 2020
Decision date	Jan 6, 2021
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong T&F Nonwoven Co., Ltd.
Location	Qingdao, CN
Contact	Minsheng Zhao
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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