

K210380 Medical surgical maskJul 8, 2021
149 days to decisionK210380 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 9, 2021
Decision date	Jul 8, 2021
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shantou T&K Medical Equipment Factory Co.,Ltd
Location	Shantou, CN
Contact	Wan Li
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Stuart Situ

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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