

K210767 Surgical Masks, Model:FE-1Jun 10, 2021
87 days to decisionK210767 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 15, 2021
Decision date	Jun 10, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Triplex Precision Medical Devices Co., Ltd.
Location	Changsha, CN
Contact	Huang Kai
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Amber Pang

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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