

K213724 Medical Surgical MaskFeb 20, 2022
86 days to decisionK213724 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k213724/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 26, 2021
Decision date	Feb 20, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Zhenheyikang Medical Instrument Co., Ltd.
Location	Xiangtan, CN
Contact	Yilin Yin
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle 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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