

K210524 Surgical MaskJul 7, 2021
134 days to decisionK210524 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210524/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 23, 2021
Decision date	Jul 7, 2021
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Holymed Products Co., Ltd.
Location	Changhou, CN
Contact	Shan Shang
510(k) history	3 submissions · 3 cleared · 2012-2021

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