

K213736 Medical Face MaskMar 31, 2022
122 days to decisionK213736 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k213736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 29, 2021
Decision date	Mar 31, 2022
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hangzhou Runheng Medical Co., Ltd.
Location	Hangzhou, CN
Contact	Yaya Lu
510(k) history	2 submissions · 2 cleared · 2022-2022

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