

K201754 JianYu Surgical MaskDec 30, 2020
184 days to decisionK201754 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 29, 2020
Decision date	Dec 30, 2020
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Jianyu Health Medical Co., Ltd.
Location	Changzhou, CN
Contact	Andy Shu
510(k) history	1 submissions · 1 cleared · 2020-2020

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