

K203455 Disposable Medical MaskSep 13, 2021
294 days to decisionK203455 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k203455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 23, 2020
Decision date	Sep 13, 2021
Days to decision	294 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujian Kang Chen Daily Necessities Co., Ltd.
Location	Quanzhou, CN
Contact	Shuyan Wang
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203455/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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