

K210256 CiRx (R) Surgical MaskAug 19, 2021
199 days to decisionK210256 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210256/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 1, 2021
Decision date	Aug 19, 2021
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Shun YE Medical Company, Ltd.
Location	Ningbo, CN
Contact	Frank Yu
510(k) history	2 submissions · 2 cleared · 2021-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210256/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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