

K203775 AIC disposable medical maskMar 12, 2021
74 days to decisionK203775 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203775/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 28, 2020
Decision date	Mar 12, 2021
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Aleen International Corporation
Location	Heyuan, CN
Contact	Can Huang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Duocare, LLC
Contact	Diana Lam

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203775/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026