

K212471 Medical Face MaskNov 4, 2021
90 days to decisionK212471 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k212471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 6, 2021
Decision date	Nov 4, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Haian Medigauze Co., Ltd.
Location	Nantong, CN
Contact	Weihua Xu
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212471/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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