

K202745 Disposable medical face maskAug 23, 2021
339 days to decisionK202745 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k202745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 18, 2020
Decision date	Aug 23, 2021
Days to decision	339 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Jingeao Electronics, Inc.
Location	Cixi, CN
Contact	Yiyun Yu
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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/k202745/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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