

K202491 Disposable Surgical Face MaskJan 6, 2021
128 days to decisionK202491 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 31, 2020
Decision date	Jan 6, 2021
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Newvalue Medical Products Co., Ltd.
Location	Taizhou, CN
Contact	Zhou Zhengguo
510(k) history	2 submissions · 2 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Medical Business Consulting Co., Ltd.
Contact	Julie Chen

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

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