

K210643 Disposable Surgical Face MaskAug 4, 2021
154 days to decisionK210643 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 3, 2021
Decision date	Aug 4, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Zhushi Pharmaceutical Group Co., Ltd.
Location	Heze, CN
Contact	Junhui Zhu
510(k) history	8 submissions · 8 cleared · 2021-2024

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](https://accessdata.fda.gov)

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