

K210409 Disposable Surgical Face MaskJul 28, 2021
167 days to decisionK210409 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 11, 2021
Decision date	Jul 28, 2021
Days to decision	167 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**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210409/> 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 26, 2026