

K212097 Disposable medical surgical maskAug 18, 2021
43 days to decisionK212097 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k212097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 6, 2021
Decision date	Aug 18, 2021
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hebei Titans Hongsen Medical Technology Co., Ltd.
Location	Nangong, CN
Contact	Chai Wu
510(k) history	7 submissions · 7 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212097/> 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 25, 2026