

K212807 Surgical MasksDec 3, 2021
91 days to decisionK212807 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212807/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 3, 2021
Decision date	Dec 3, 2021
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Weihai Hongyu Nonwoven Fabric Products Co., Ltd.
Location	Weihai, KM
Contact	Bin Dong
510(k) history	6 submissions · 6 cleared · 2012-2022

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/k212807/> 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