

K210102 Topwide Surgical Face MaskDec 17, 2021
337 days to decisionK210102 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 14, 2021
Decision date	Dec 17, 2021
Days to decision	337 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Topwide (Hubei) Medical Products Manufacturer
Location	Xiantao, CN
Contact	Shoucheng Zhang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Lee and Xiao
Contact	Jimmy Wu

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