

K212997 Surgical MaskJan 14, 2022
116 days to decisionK212997 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212997/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 20, 2021
Decision date	Jan 14, 2022
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Zhizhen Biological Medical Co., Ltd.
Location	Guangzhou, CN
Contact	Caiyun Zhou
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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