

**K222697 Disposable Medical Face Mask (DF3-001)**Nov 4, 2022  
58 days to decisionK222697 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k222697/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 7, 2022
Decision date	Nov 4, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wellmed Dental Medical Supply Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Tang Renxian
510(k) history	3 submissions · 3 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Jarvis Wu

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

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