

**K223045 3-Ply Disposable Medical Mask**Dec 7, 2022  
69 days to decisionK223045 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k223045/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 29, 2022
Decision date	Dec 7, 2022
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wealth Lead Industrial Limited</b>
Location	Hong Kong, CN
Contact	Ethel Chiu Man Mok
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223045/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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