

**K223055 Disposable Medical Face Mask**Dec 5, 2022  
67 days to decisionK223055 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k223055/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 29, 2022
Decision date	Dec 5, 2022
Days to decision	67 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Xiantao Zhuobo Industrial Co., Ltd.</b>
Location	Xiantao, CN
Contact	Chen Xiaodong
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

---

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)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223055/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026