

**K202205 Surgical Face Mask**Mar 9, 2021  
216 days to decisionK202205 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202205/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 5, 2020
Decision date	Mar 9, 2021
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Jiangsu Micsafe Medical Technology Co., Ltd.</b>
Location	Yancheng, CN
Contact	Tony Yang
510(k) history	5 submissions · 5 cleared · 2018-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Share Info (Guangzhou) Medical Consultant , Ltd.</b>
Contact	Cassie Lee

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/k202205/> 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 26, 2026