

**K202277 Surgical Face Mask**Sep 25, 2020  
45 days to decisionK202277 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k202277/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 11, 2020
Decision date	Sep 25, 2020
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Jiangxi 3I Medical Products Group Co., Ltd.</b>
Location	Nanchang City, CN
Contact	Ge Zhang
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Irc</b>
Contact	Charles Mack

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/k202277/> 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 June 29, 2026