

**K212610 Surgical Face Mask**Jan 26, 2022  
162 days to decisionK212610 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k212610/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 17, 2021
Decision date	Jan 26, 2022
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Foshan Nanhai Plus Medical Co, Ltd.</b>
Location	Dover, DE, US
Contact	Suyi Li
510(k) history	8 submissions · 8 cleared · 2015-2022

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Guangzhou Osmunda Medical Device Technical Service Co., Ltd.</b>
Contact	Olivia Meng

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/k212610/> 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