

**K211832 Fluid Resistant Procedure Mask, Fluid Resistant Surgical Mask**Sep 8, 2021  
86 days to decisionK211832 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k211832/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 14, 2021
Decision date	Sep 8, 2021
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Zhejiang Lanhine Medical Products, Ltd.</b>
Location	Cixi, CN
Contact	Jerry Gu
510(k) history	2 submissions · 2 cleared · 2021-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Ivy Wang

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211832/> 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