

**K211341 Blue Nitrile Exam Gloves**Jul 29, 2021  
87 days to decisionK211341 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k211341/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 3, 2021
Decision date	Jul 29, 2021
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Jiangxi Surefine Medical Co., Ltd.</b>
Location	Shangrao, CN
Contact	Steve Zhu
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle 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](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211341/> 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