

**K212485 Disposable Nitrile Examination gloves**Nov 5, 2021  
88 days to decisionK212485 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212485/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 9, 2021
Decision date	Nov 5, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Fujian Yuanxin Safety Protection Technology Co., Ltd.</b>
Location	Ningde, CN
Contact	Alan Wu
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/k212485/> 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