

**K212661 Disposable Nitrile Examination Glove**Nov 19, 2021  
88 days to decisionK212661 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k212661/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 23, 2021
Decision date	Nov 19, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Inner Mongolia Cureguard Medical Technology Co., Ltd.</b>
Location	Baotou, CN
Contact	Guo Hua
510(k) history	3 submissions · 3 cleared · 2021-2022

**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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212661/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026