

K212833 Disposable Nitrile Examination GlovesFeb 28, 2022
174 days to decisionK212833 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212833/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 7, 2021
Decision date	Feb 28, 2022
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chifeng Huawei Medical Science&Technology Co., Ltd.
Location	Chifeng, CN
Contact	Li Xiaohong
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
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.netDevice record: <https://www.510kdatabase.net/k212833/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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