

K212921 Nitrile Examination Gloves Powder FreeDec 24, 2021
101 days to decisionK212921 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 14, 2021
Decision date	Dec 24, 2021
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Standard Health Co.,Ltd
Location	Zhangjiagang City, CN
Contact	Lu Tao
510(k) history	1 submissions · 1 cleared · 2021-2021

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/k212921/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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