

K212578 Nitrile disposable examination glovesDec 2, 2021
108 days to decisionK212578 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212578/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 16, 2021
Decision date	Dec 2, 2021
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xingyu Medical Tech Co., Ltd.
Location	Weifang, CN
Contact	Cathrine Luan
510(k) history	4 submissions · 4 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Eva Li

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/k212578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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