

K203436 Disposable Nitrile Examination GlovesApr 28, 2021
156 days to decisionK203436 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k203436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 23, 2020
Decision date	Apr 28, 2021
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Zhushi Pharmaceutical Group Co., Ltd.
Location	Heze, CN
Contact	Junhui Zhu
510(k) history	8 submissions · 8 cleared · 2021-2024

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/k203436/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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