

K232576 Medical Nitrile Examination GlovesNov 21, 2023
88 days to decisionK232576 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k232576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 25, 2023
Decision date	Nov 21, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Complete Sincerity Medical New Materials Co., Ltd.
Location	Suqian, CN
Contact	Shangjun Xie
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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