

K211719 ZinRom Nitrile examination glovesOct 6, 2021
124 days to decisionK211719 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 4, 2021
Decision date	Oct 6, 2021
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Xingrong Medical Technology Co., Ltd.
Location	Changzhou, CN
Contact	Ray Lei
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Amber Pang

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

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