

K211927 Nitrile examination glovesOct 12, 2021
112 days to decisionK211927 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k211927/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 22, 2021
Decision date	Oct 12, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fitone Latex Products Co., Ltd. Guangdong
Location	Zhanjiang, CN
Contact	Christine Ou
510(k) history	4 submissions · 4 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Stuart Situ

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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