

K213044 Nitrile Examination GlovesJan 21, 2022
121 days to decisionK213044 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 22, 2021
Decision date	Jan 21, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Huayuan Medical Technology Co., Ltd.
Location	Dongtai, CN
Contact	Yun Gao
510(k) history	2 submissions · 2 cleared · 2021-2022

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](https://accessdata.fda.gov)

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