

K210106 Nitrile Examination GlovesApr 7, 2021
82 days to decisionK210106 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 15, 2021
Decision date	Apr 7, 2021
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhenjiang Huayang Latex Products Co., Ltd.
Location	Yangzhong, CN
Contact	Han Sheng
510(k) history	1 submissions · 1 cleared · 2021-2021

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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