

K223004 Disposable Nitrile Examination GlovesDec 4, 2022
66 days to decisionK223004 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k223004/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 29, 2022
Decision date	Dec 4, 2022
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangxi Handspro Products Solutions Co., Ltd.
Location	Jiujiang City, CN
Contact	Jun Yin
510(k) history	2 submissions · 2 cleared · 2022-2022

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223004/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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