

K223280 Disposable Nitrile GlovesMay 8, 2023
196 days to decisionK223280 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k223280/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 24, 2022
Decision date	May 8, 2023
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Holik Asia Group Co.,Ltd
Location	Xuancheng, CN
Contact	Monica Zhou
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Spica Management Consulting Co., Ltd.
Contact	Libray Chang

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/k223280/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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