

K232008 Disposable Medical Examination Nitrile GlovesAug 8, 2023
33 days to decisionK232008 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k232008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 6, 2023
Decision date	Aug 8, 2023
Days to decision	33 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Raxwell Industrial, LLC
Location	Richmond, TX, US
Contact	Xianda Yao
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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/k232008/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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