

K221877 Powder-Free Nitrile Examination Glove, Non-SterileJul 23, 2022
25 days to decisionK221877 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k221877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 28, 2022
Decision date	Jul 23, 2022
Days to decision	25 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Goodgloves Industries Sdn Bhd
Location	Seremban, MY
Contact	Yee Kam Lin
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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/k221877/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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