

**K230314 Sterile Powder Free Nitrile Examination Gloves (Blue, Black & White Colors)**Aug 16, 2023  
191 days to decisionK230314 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k230314/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 6, 2023
Decision date	Aug 16, 2023
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>New Era Medicare Sdn. Bhd.</b>
Location	Teluk Intan, MY
Contact	Fatin Nor Irdina binti Ahmad Fauzi
510(k) history	3 submissions · 3 cleared · 2022-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230314/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026