

**K210588 Black Nitrile Powder Free Patient Examination Glove,  
Non Sterile**Oct 31, 2021  
247 days to decisionK210588 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k210588/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 26, 2021
Decision date	Oct 31, 2021
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Onetexx Sdn Bhd</b>
Location	Kamunting, MY
Contact	Freddy Low
510(k) history	7 submissions · 7 cleared · 2021-2022

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210588/> 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 26, 2026