

**K210375 Powder Free Blue Nitrile Examination Glove**Jun 21, 2021  
133 days to decisionK210375 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k210375/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 8, 2021
Decision date	Jun 21, 2021
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Duramitt Sdn Bhd</b>
Location	Kulim, MY
Contact	Terence Lim
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210375/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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