

**K210366 Blue Nitrile Powder Free Patient Examination Glove,
Non Sterile**May 7, 2021
88 days to decisionK210366 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 8, 2021
Decision date	May 7, 2021
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Emergo Global Representation
Contact	Michael Van Der Woude

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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