

**K212011 Vinyl Powder Free Examination Glove**Feb 14, 2022  
231 days to decisionK212011 · Product code: **LYZ** · General Hospital  
Source: <https://www.510kdatabase.net/k212011/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Jun 28, 2021
Decision date	Feb 14, 2022
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Top Glove Vietnam Company Limited</b>
Location	Bau Bang, VN
Contact	Natrisya Nur Binti Abdul Rahman
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Tg Medical USA (Inc)</b>
Contact	David Lim

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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