

**K211354 Disposable Synthetic Vinyl Nitrile Examination Glove**Aug 8, 2021  
97 days to decisionK211354 · Product code: LYZ · General Hospital  
Source: <https://www.510kdatabase.net/k211354/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	May 3, 2021
Decision date	Aug 8, 2021
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Cureguard Glove Co., Ltd.</b>
Location	Haidian District, Beijing, CN
Contact	Guo Hua
510(k) history	11 submissions · 11 cleared · 2007-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle Wang

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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