

K210684 Disposable Nitrile Medical Examination GloveJul 20, 2021
134 days to decisionK210684 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k210684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 8, 2021
Decision date	Jul 20, 2021
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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

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