

K212840 Nitrile Gloves (Model: NE01)Dec 11, 2021
95 days to decisionK212840 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 7, 2021
Decision date	Dec 11, 2021
Days to decision	95 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Byd Auto Industry Company Limited
Location	Shenzhen, CN
Contact	Liu Jiangling
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Share Info (Guangzhou) Medical Consultant , Ltd.
Contact	Cassie Lee

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

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