

K212029 Disposable Medical Nitrile Examination Gloves (non-sterile)Nov 16, 2021
140 days to decisionK212029 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212029/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 29, 2021
Decision date	Nov 16, 2021
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taizhou Kangjian Medical Equipments Co., Ltd.
Location	Taizhou, CN
Contact	Hua Cong
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Cytech (Shenzhen) Enterprise Management Consulting Co., Ltd.
Contact	Helen Nan

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

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