

K213187 Disposable Nitrile Medical Powder-free GloveJan 3, 2022
96 days to decisionK213187 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213187/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 29, 2021
Decision date	Jan 3, 2022
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fujian Chunhui Medical Supply Co., Ltd.
Location	Longyan City, CN
Contact	Jing Cai
510(k) history	1 submissions · 1 cleared · 2022-2022

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](https://accessdata.fda.gov)

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