

K221108 Nitrile Medical Examination GlovesJul 12, 2022
88 days to decisionK221108 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k221108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 15, 2022
Decision date	Jul 12, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Fulewei Electronic Technology Co.,Ltd
Location	Fuyang, CN
Contact	Beina Gong
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221108/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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