

K220066 Medical Nitrile Examination GlovesApr 3, 2022
83 days to decisionK220066 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 10, 2022
Decision date	Apr 3, 2022
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hunan Zhenheyikang Medical Instrument Co., Ltd.
Location	Xiangtan, CN
Contact	Yilin Yin
510(k) history	2 submissions · 2 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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