

K213600 Medical nitrile examination gloves (Model: SH001)Feb 19, 2022
96 days to decisionK213600 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k213600/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Nov 15, 2021
Decision date	Feb 19, 2022
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangxi Sanhao Medical Instruments Co.,Ltd
Location	Ji'An, CN
Contact	Wangfenfang No Last Name provided
510(k) history	2 submissions · 2 cleared · 2022-2022

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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