

K220442 Synguard Nitrile Exam GloveMay 12, 2022
85 days to decisionK220442 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 16, 2022
Decision date	May 12, 2022
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tianjin Aoshang Outdoor Equipment Co., Ltd.
Location	Tianjin, CN
Contact	Xiaoning Zhang
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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

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