

K231365 Nitrile Patient Examination Gloves with Hyaluronic Acid Blue Colored and Tested for Use with Chemotherapy Drugs and Fentanyl Citrate, aka Synguard C+ Nitrile Exam Gloves

Mar 1, 2024
295 days to decision

K231365 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k231365/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 11, 2023
Decision date	Mar 1, 2024
Days to decision	295 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Intco Medical Products Co., Ltd.
Location	Huaibei, CN
Contact	Max li
510(k) history	4 submissions · 4 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	Intco Medical Industries, Inc.
Contact	Deze Wang

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k231365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026