

K222129 Nitrile Examination Powder Free Glove, Blue Tested For Use With 32 Chemotherapy Drugs and Fentanyl Permeation Resistance Claim, Nitrile Examination Powder Free Glove, Black Tested For Use With 32 Chemotherapy Drugs and Fentanyl Permeation Resistance Claim

Feb 10, 2023
207 days to decision

K222129 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k222129/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 18, 2022
Decision date	Feb 10, 2023
Days to decision	207 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Top Glove Medical (Thailand) Co., Ltd.
Location	Songkhla, TH
Contact	Shahana Parveen Binti Ridzam Shah
510(k) history	3 submissions · 3 cleared · 2002-2023

REGULATORY CONSULTANT

Consulting firm	Tg Medical (Usa), Inc.
Contact	David Lim

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