

K202003 Nitrile Powder Free Examination Glove, Blue Tested for Use with 32 Chemotherapy Drugs and Fentanyl Permeation Resistance Claim

Feb 24, 2021
219 days to decisionK202003 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k202003/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 20, 2020
Decision date	Feb 24, 2021
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Gmp Medicare Sdn. Bhd.
Location	Klang, MY
Contact	Noraini Binti
510(k) history	3 submissions · 3 cleared · 2017-2025

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)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202003/> 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 27, 2026