

K212850 ComfortPro Blue Nitrile Examination Gloves Powder FreeDec 10, 2021
94 days to decisionK212850 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 7, 2021
Decision date	Dec 10, 2021
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Thai Rubber Industry Company Limited
Location	Pluakdaeng, TH
Contact	Supawadee Phoungthong
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group , Ltd.
Contact	Manoj Zacharias

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/k212850/> 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 25, 2026