

K193581 Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Lilac, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Orchid, Non-Sterile, Powder Free Nitrile Exam Glove Tested for use with Chemotherapy Drugs - Oyster

Mar 20, 2020
88 days to decision

K193581 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k193581/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 23, 2019
Decision date	Mar 20, 2020
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sri Trang Gloves (Thailand) Public Company Limited
Location	Hatyai, TH
Contact	Jarinya Jirojkul
510(k) history	8 submissions · 8 cleared · 2020-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193581/> 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