

K203191 LYDUS Nitrile Examination Gloves, Powder FreeFeb 12, 2021
108 days to decisionK203191 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k203191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 27, 2020
Decision date	Feb 12, 2021
Days to decision	108 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nathan Trading Co., Ltd.
Location	Nathan District, TH
Contact	Chansamone Saiyasak
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Global Quality and Regulatory Services
Contact	Abdel B. Halim

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203191/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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