

K190736 Disposable Powder Free Nitrile Examination Glove, Blue Color, Tested For Use With Chemotherapy DrugsDec 23, 2019
277 days to decisionK190736 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k190736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 21, 2019
Decision date	Dec 23, 2019
Days to decision	277 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ever Growth (Vietnam) Co. , Ltd.
Location	Long Khanh Township, VN
Contact	Ming Lee
510(k) history	4 submissions · 4 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	Elizabeth Deng
Contact	Elizabeth Deng

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/k190736/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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