

K182383 Non-Sterile, PF Nitrile Examination Gloves, Tested for Use with Chemotherapy Drugs-BlueMar 19, 2019
200 days to decisionK182383 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k182383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Aug 31, 2018
Decision date	Mar 19, 2019
Days to decision	200 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Yty Industry (Manjung) Sdn Bhd
Location	Selangor, Malaysia, MY
Contact	Punitha Samy
510(k) history	27 submissions · 27 cleared · 1989-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182383/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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