

**K172864 Non-Sterile Powder Free Blue Nitrile Examination
Gloves Tested for Use with Chemotherapy Drugs**May 2, 2018
224 days to decisionK172864 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k172864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Sep 20, 2017
Decision date	May 2, 2018
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Maxter Glove Manufacturing Sdn Bhd
Location	41050 Klang, Selangor, MY
Contact	Yap Peak Geeh
510(k) history	9 submissions · 9 cleared · 2001-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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