

K151390 Powder Free Nitrile Examination Gloves Tested For Use With Chemotherapy Drugs

May 2, 2016
342 days to decisionK151390 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k151390/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	May 26, 2015
Decision date	May 2, 2016
Days to decision	342 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/k151390/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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