

K220545 Powder Free Nitrile Examination Gloves, Blue, Tested for use with Chemotherapy Drugs

May 26, 2022
90 days to decision

K220545 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k220545/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Feb 25, 2022
Decision date	May 26, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	HI Rubber Industries Sdn Bhd
Location	Kuala Pilah, Negeri Sembilan, MY
Contact	Noorzaliza Ahmad
510(k) history	7 submissions · 7 cleared · 2007-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k220545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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