

K151343 Nitrile Powder Free Examination Gloves Tested for Use with Chemotherapy Drugs (white, blue, orange)

Aug 24, 2015
97 days to decision

K151343 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k151343/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 19, 2015
Decision date	Aug 24, 2015
Days to decision	97 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega NGC Sdn. Bhd.
Location	Bandar Sri Damansara, MY
Contact	KUAN MUN LEONG
510(k) history	28 submissions · 28 cleared · 2014-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151343/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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