

K163017 Nitrile Blue Powder Free Examination Gloves with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs

Mar 22, 2017
145 days to decision

K163017 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k163017/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Oct 28, 2016
Decision date	Mar 22, 2017
Days to decision	145 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gmp Medicare Sdn. Bhd.
Location	Klang, MY
Contact	EVA VINONI BT MUSTAFA
510(k) history	3 submissions · 3 cleared · 2017-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k163017/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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