

K150593 Nitrile Powder Free Examination Glove with Low Dermatitis Potential Claim (Blue)

Jun 9, 2015
92 days to decision

K150593 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k150593/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Mar 9, 2015
Decision date	Jun 9, 2015
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	KUAN KAM HON
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k150593/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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