

K160562 Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Tested for Use with Chemotherapy Drugs

Oct 13, 2016
227 days to decision

K160562 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k160562/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 29, 2016
Decision date	Oct 13, 2016
Days to decision	227 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Snd. Bhd.
Location	Bestari Jaya, MY
Contact	KUAN KAM HON
510(k) history	2 submissions · 2 cleared · 2012-2016

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k160562/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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