

K162819 Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Tested for Use with Chemotherapy Drugs

Jan 9, 2017
95 days to decision

K162819 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k162819/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 6, 2016
Decision date	Jan 9, 2017
Days to decision	95 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/k162819/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026