

K142805 Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP Skin Protectant Drug- Dark Violet Blue (DVBU)Dec 18, 2014
80 days to decisionK142805 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k142805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 29, 2014
Decision date	Dec 18, 2014
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdb. Bhd.
Location	Bandar Sri Damansara, MY
Contact	KUAN KAM HON
510(k) history	4 submissions · 4 cleared · 2014-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k142805/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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