

K161215 Brightway Brand Nitrile Examination Gloves, Powder Free, [Sterling/Grey] Tested For Use With Chemotherapy DrugsDec 21, 2016
236 days to decisionK161215 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k161215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 29, 2016
Decision date	Dec 21, 2016
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Brightway Holdings Sdn. Bhd.
Location	Klang, Selangor Darul Ehsan, MY
Contact	G. BASKARAN
510(k) history	24 submissions · 24 cleared · 1999-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161215/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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