

**K081315 POWDER FREE NITRILE EXAMINATION GLOVES
TESTED FOR USE WITH CHEMOTHERAPY DRUGS (PINK,
BLACK, GREY, AND BLUE PEPPERMENT)**

Aug 11, 2008
94 days to decision

K081315 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k081315/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 9, 2008
Decision date	Aug 11, 2008
Days to decision	94 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gx Corporation Sdn Bhd
Location	Klang, Selangor, MY
Contact	FOO K PU
510(k) history	18 submissions · 18 cleared · 2007-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k081315/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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