

**K113100 POWDER FREE NITRILE EXAMINATION GLOVES  
TESTED FOR USE WITH CHEMOTHERAPY DRUGS**

Feb 6, 2012  
110 days to decision

K113100 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k113100/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 19, 2011
Decision date	Feb 6, 2012
Days to decision	110 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Maxter Glove Manufacturing Sdn Bhd</b>
Location	41050 Klang, Selangor, MY
Contact	YAP P GEEH
510(k) history	9 submissions · 9 cleared · 2001-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k113100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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