

**K182089 Powder Free Blue Nitrile Examination Gloves - Tested for Use with Chemotherapy Drugs**

Jul 30, 2019  
362 days to decision

K182089 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k182089/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 2, 2018
Decision date	Jul 30, 2019
Days to decision	362 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Platinum Glove Industries Sdn. Bhd.</b>
Location	Kuala Lumpur, MY
Contact	Foo Khon Pu
510(k) history	6 submissions · 6 cleared · 2005-2019

---

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

Device record: <https://www.510kdatabase.net/k182089/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 22, 2026