

# K192954 Power Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs and Fentanyl

Jun 19, 2020  
242 days to decisionK192954 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k192954/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 21, 2019
Decision date	Jun 19, 2020
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Comfort Rubber Gloves Industries Sdn. Bhd.</b>
Location	Matang, MY
Contact	Ng Kok Howe
Website	<a href="http://www.comfort-rubber.com.my/">http://www.comfort-rubber.com.my/</a>
510(k) history	15 submissions · 15 cleared · 1994-2025

Comfort Rubber Gloves Industries Sdn. Bhd. manufactures examination gloves for healthcare settings. The company operates with a manufacturing facility in Matang, Malaysia. The company has received FDA 510(k) clearances from total submissions since 1994. All submissions focus on General Hospital devices. The latest clearance was granted in 2025, confirming active regulatory engagement. Product specialization centers on powder-free examination gloves in multiple materials and colors. Recent cleared devices include nitrile and natural rubber latex formulations. Many products...

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

Device record: <https://www.510kdatabase.net/k192954/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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