

## K241528 Nitrile Powder Free Examination Gloves (Blue), Non-Sterile Low Dermatitis Potential

Aug 6, 2024  
68 days to decision

K241528 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k241528/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 30, 2024
Decision date	Aug 6, 2024
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Comfort Rubber Gloves Industries Sdn. Bhd.</b>
Location	Matang, MY
Contact	Sumathi Saravana Sami
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...

### REGULATORY CONSULTANT

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Consulting firm	<b>T. Cunningham Consulting &amp; Associates, LLC</b>
Contact	Terrell Cunningham

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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

Device record: <https://www.510kdatabase.net/k241528/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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