

**K110297 POWDER FREE NITRILE (BLACK) EXAMINATION GLOVES**Jun 15, 2011  
134 days to decisionK110297 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k110297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 1, 2011
Decision date	Jun 15, 2011
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Comfort Rubber Gloves Industries Sdn. Bhd.</b>
Location	Matang, MY
Contact	TAN KENG BENG
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/k110297/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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