

K171541 Powder Free Nitrile Examination Gloves (Orange)Sep 20, 2017
117 days to decisionK171541 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k171541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 26, 2017
Decision date	Sep 20, 2017
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Comfort Rubber Gloves Industries Sdn. Bhd.
Location	Matang, MY
Contact	Chan Yew Men
Website	http://www.comfort-rubber.com.my/
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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