

K190080 Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs Labeling Claim (Black)

Jun 27, 2019
162 days to decisionK190080 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k190080/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 16, 2019
Decision date	Jun 27, 2019
Days to decision	162 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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Device record: <https://www.510kdatabase.net/k190080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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