

K180476 Powder Free Nitrile Examination Gloves Tested for Use with Chemotherapy Drugs

May 15, 2018
82 days to decisionK180476 · Product code: LZC · General Hospital
Source: <https://www.510kdatabase.net/k180476/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medical Glove, Specialty (LZC)
Date received	Feb 22, 2018
Decision date	May 15, 2018
Days to decision	82 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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