

K001613 COMFIT CHEMO PLUS PLUS POWDER FREE NITRILE EXAMINATION GLOVES (TESTED FOR USE WITH CHEMOTHERAPY DRUGS)

Nov 22, 2000
181 days to decision

K001613 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k001613/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 25, 2000
Decision date	Nov 22, 2000
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wrp Asia Pacific Sdn. Bhd.
Location	Salak Tinggi, Sepang Selangor, MY
Contact	YUE WHA CHOW
510(k) history	46 submissions · 46 cleared · 1999-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k001613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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