FDA 510(k) Premarket Notification

CLEARED

Nov 28, 2000
144 days to decision

K002064 COMFIT CHEMO PLUS POWDER FREE BLUE NITRILE EXAMINATION GLOVES, NON STERILE (TESTED FOR USE WITH CHEMOTHERAPY DRUG) LABEL

K002064 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k002064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jul 7, 2000
Decision date	Nov 28, 2000
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k002064/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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