FDA 510(k) Premarket Notification

K012048 POWDER FREE NEOPRENE EXAMINATION GLOVES, NON STERILE

CLEARED

Aug 16, 2001
48 days to decision

K012048 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k012048/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 29, 2001
Decision date	Aug 16, 2001
Days to decision	48 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/k012048/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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