FDA 510(k) Premarket Notification

CLEARED

K003653 STERILE POWDER FREE POLYMER COATED LATEX EXAMINATION GLOVES, WITH PROTEIN LABELING CLAIM (50 MICROGRAM OR LESS)

Jan 26, 2001
60 days to decision

K003653 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k003653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 27, 2000
Decision date	Jan 26, 2001
Days to decision	60 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/k003653/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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