

K992417 ROYAL SHIELD NON-STERILE POWDERED LATEX EXAMINATION GLOVES (PROTEIN LABELING CLAIM) 200 MCGM OR LESS OF TOTAL WATER EXTR

Sep 13, 1999
55 days to decision

K992417 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k992417/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 20, 1999
Decision date	Sep 13, 1999
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shield Gloves Manufacturer (M) Sdn Bhd
Location	Petaling Jaya, MY
Contact	E.J. Smith
510(k) history	18 submissions · 18 cleared · 1994-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k992417/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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