

K991616 CHLORINATED POWDER-FREE LATEX EXAMINATION GLOVE WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)

Jul 14, 1999
65 days to decision

K991616 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k991616/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 10, 1999
Decision date	Jul 14, 1999
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	KUAN KAM HON
510(k) history	61 submissions · 61 cleared · 1989-2020

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k991616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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