

K011995 POLYMER COATED LATEX MEDICAL EXAMINATION GLOVES WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)

Jul 31, 2001
35 days to decision

K011995 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k011995/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 26, 2001
Decision date	Jul 31, 2001
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Quality Latex Products Malaysia Sdn Bhd
Location	Ipoh. Perak, MY
Contact	SHARENE WAN
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k011995/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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