

K003213 ALMATEX POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTIEN LABELING CLAIM 50 MICROGRAMS OR LESS

Nov 29, 2000
47 days to decision

K003213 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k003213/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 13, 2000
Decision date	Nov 29, 2000
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Concept Rubber Products Sdn Bhd
Location	Penang, MY
Contact	TEOH HUN LIM
510(k) history	2 submissions · 2 cleared · 1989-2000

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k003213/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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