

K050527 POWDERED LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM (CONTAINS 200 MICROGRAMS OR LESS OF TOTAL WATER EXTRACTABL

Mar 18, 2005
16 days to decision

K050527 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k050527/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 2, 2005
Decision date	Mar 18, 2005
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spi Gloves Sdn. Bhd.
Location	Ipoh 30450, MY
Contact	CHOOI FONG CHUN
510(k) history	7 submissions · 7 cleared · 2005-2005

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k050527/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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