

**K070821 POWDERED NATURAL RUBBER LATEX
EXAMINATION GLOVES (PROTEIN LABEL CLAIM) 200
MICROGRAMS OR LESS OF TOTAL WATER EXTRACTABLE**

May 10, 2007
45 days to decision

K070821 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k070821/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 26, 2007
Decision date	May 10, 2007
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtexx Manufacturing Sdn. Bhd.
Location	Kamunting, Taiping, Perak, MY
Contact	OOI LOON SENG
510(k) history	4 submissions · 4 cleared · 2007-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k070821/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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