

**K001475 HEALTH-PLUS, SANITEX, RELIANCE, POWDERED
LATEX EXAM GLOVES CONTAINS 100 MICROGRAMS OR LESS
OF TOTAL WATER EXTRACTABLE PR**

Jun 13, 2000
33 days to decision

K001475 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k001475/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 11, 2000
Decision date	Jun 13, 2000
Days to decision	33 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pwa Industries Sdn. Bhd.
Location	Selangor Darul Ehsan, MY
Contact	AZHARSYAH M YASSIN
510(k) history	11 submissions · 11 cleared · 1995-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k001475/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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