

**K001485 HEALTH-PLUS, SANITEX, RELIANCE, POWDER-FREE
LATEX EXAMINATION GLOVES**Jun 13, 2000
32 days to decisionK001485 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k001485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	May 12, 2000
Decision date	Jun 13, 2000
Days to decision	32 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.netDevice record: <https://www.510kdatabase.net/k001485/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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