

**K973913 MEDI-PLUS, HEALTH-PLUS, SANITEX, RELIANCE**Dec 18, 1997  
65 days to decision

K973913 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k973913/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 14, 1997
Decision date	Dec 18, 1997
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pwa Industries Sdn. Bhd.</b>
Location	Selangor Darul Ehsan, MY
Contact	AZMAN ISMAIL
510(k) history	11 submissions · 11 cleared · 1995-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973913/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 4, 2026