

**K003350 HEALTH-PLUS, SANITEX, RELIANCE MULTIPLY
POWDER FREE POLYMER AND NITRILE COATED (BLUE)**Apr 5, 2001
161 days to decisionK003350 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k003350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 26, 2000
Decision date	Apr 5, 2001
Days to decision	161 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pamitex Industries Sdn Bhd
Location	Darul Khusus, MY
Contact	SAID AWANG
510(k) history	19 submissions · 19 cleared · 1999-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003350/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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