

K011895 POWDER-FREE MULTI-PLY LATEX EXAMINATION GLOVES, POLYMER COATED ON OUTSIDE AND NITRILE COATED ON INSIDE, BLUE COLOR WITHJul 9, 2001
21 days to decisionK011895 · Product code: LYY · General Hospital
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jun 18, 2001
Decision date	Jul 9, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011895/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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