

K010077 HEALTH-PLUS, SANITEX, RELIANCE POWDER-FREE NITRILE EXAMINATION GLOVES

Feb 28, 2001
49 days to decision

K010077 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k010077/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 10, 2001
Decision date	Feb 28, 2001
Days to decision	49 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.net

Device record: <https://www.510kdatabase.net/k010077/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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