

K951921 SCINITREX (GREEN POWDERED NITRILE EXAMINATION GLOVES)Oct 30, 1995
189 days to decisionK951921 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k951921/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 24, 1995
Decision date	Oct 30, 1995
Days to decision	189 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wembley Rubber Products (M) Sdn Bhd
Location	Kuala Lumpur, Malaysia, MY
Contact	ONG GHEE CHEE
510(k) history	61 submissions · 61 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951921/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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