

**K971666 SMART - FIT, PREPOWDERED NITRILE EXAMINATION GLOVES**Jul 3, 1997  
58 days to decisionK971666 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k971666/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 6, 1997
Decision date	Jul 3, 1997
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sj Medical Products (M) Sdn Bhd</b>
Location	Klang, Selangor, MY
Contact	FOO KHON PU
510(k) history	5 submissions · 5 cleared · 1994-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971666/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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