

**K984311 NBR4 MILS NITRILE POWDER FREE EXAMINATION  
GLOVES NON-STERILE**

Feb 9, 1999  
69 days to decision

K984311 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k984311/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 2, 1998
Decision date	Feb 9, 1999
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sumirubber Industries (Kedah) Sdn. Bhd.</b>
Location	Sungai Petani, Kedah, MY
Contact	HIDEAKI OCHIAI
510(k) history	3 submissions · 3 cleared · 1989-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k984311/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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