

**K980419 OMNI FLEX NITRILE EXAMINATION GLOVE, POWDER-FREE**Mar 13, 1998  
38 days to decisionK980419 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k980419/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 3, 1998
Decision date	Mar 13, 1998
Days to decision	38 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Omnigrace (Thailand) , Ltd.</b>
Location	North Canton, OH, US
Contact	WILLIAM E PATTON
510(k) history	12 submissions · 12 cleared · 1998-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980419/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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