

**K994246 OMNI GRACE NITRILE, BLUE, EXAMINATION GLOVE,
POWDER-FREE, POLYMER COATED**Jan 31, 2000
46 days to decisionK994246 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k994246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 16, 1999
Decision date	Jan 31, 2000
Days to decision	46 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Omnigrace , Ltd.
Location	Canton, OH, US
Contact	WILLIAM E PATTON
510(k) history	8 submissions · 8 cleared · 1997-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k994246/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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