

**K012402 OMNI GRACE LATEX EXAMINATION GLOVE,
POWDER FREE, POLYMER COATED WITH PROTEIN CLAIM**Oct 12, 2001
77 days to decisionK012402 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k012402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 27, 2001
Decision date	Oct 12, 2001
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012402/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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