

**K002922 OMNI GRACE LATEX EXAMINATION GLOVE,
POWDERED, WITH PROTEIN CLAIM (200 MICROGRAMS OR
LESS)**Oct 16, 2000
27 days to decisionK002922 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k002922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 19, 2000
Decision date	Oct 16, 2000
Days to decision	27 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/k002922/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 3, 2026