

**K011765 SUNMAX BLUE NITRILE POWDER-FREE
EXAMINATION GLOVE**Aug 16, 2001
70 days to decisionK011765 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k011765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 7, 2001
Decision date	Aug 16, 2001
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sunmax Enterprise Shanghai Co. , Ltd.
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	5 submissions · 5 cleared · 1996-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011765/> 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 June 22, 2026