

**K011717 SUNMAX BLUE NITRILE POWDERED EXAMINATION GLOVES**

Aug 14, 2001  
71 days to decision

K011717 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k011717/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jun 4, 2001
Decision date	Aug 14, 2001
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k011717/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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