

**K010297 SENSICARE SYNTHETIC POWDER FREE SURGICAL GLOVES (POLY ISOPRENE)**

Feb 16, 2001  
16 days to decision

K010297 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k010297/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Jan 31, 2001
Decision date	Feb 16, 2001
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Maxxim Medical</b>
Location	Arlington, TX, US
Contact	WUNAN HUANG
510(k) history	26 submissions · 25 cleared · 1994-2002

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

Device record: <https://www.510kdatabase.net/k010297/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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