

**K163041 Powder Free Polychloroprene Examination Gloves-  
Pink with Aloe Vera and Vitamin E**

Feb 22, 2017  
114 days to decision

K163041 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k163041/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Oct 31, 2016
Decision date	Feb 22, 2017
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pt. Medisafe Technologies</b>
Location	Medan, ID
Contact	DEEPAK BANG
510(k) history	19 submissions · 19 cleared · 2001-2020

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

Device record: <https://www.510kdatabase.net/k163041/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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