

K161099 Powder Free Nitrile Examination Gloves, BlackFeb 23, 2017
310 days to decisionK161099 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k161099/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Apr 19, 2016
Decision date	Feb 23, 2017
Days to decision	310 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pt. Maja Agung Latexindo
Location	Indonesia, ID
Contact	IMELDA SHAMROCK
510(k) history	11 submissions · 11 cleared · 1990-2022

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