

**K090464 BLACK NITRILE EXAMINATION GLOVES, POWDER
FREE, NON STERILE**

Apr 23, 2009
59 days to decision

K090464 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k090464/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 23, 2009
Decision date	Apr 23, 2009
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pt Mahakarya Inti Buana
Location	Morawa, Sumut, ID
Contact	AZMAN ISMAIL
510(k) history	9 submissions · 9 cleared · 2005-2011

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090464/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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