

K053366 NITRILE EXAMINATION GLOVES, POWDERED, NON STERILE

Mar 30, 2006
115 days to decision

K053366 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k053366/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 5, 2005
Decision date	Mar 30, 2006
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k053366/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026