FDA 510(k) Premarket Notification

CLEARED

Aug 12, 2011
95 days to decision

K111300 SENSTOUCH NITRILE EXAMINATION GLOVES, POWDER FREE, NON STERILE (GREEN, ORANGE, VIOLET AND WHITE)

K111300 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k111300/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 9, 2011
Decision date	Aug 12, 2011
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k111300/ 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