FDA 510(k) Premarket Notification

K042239 FLEXISKIN POWDER FREE NITRILE EXAMINATION GLOVES, NON STERILE

CLEARED

Dec 16, 2004
120 days to decision

K042239 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k042239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 18, 2004
Decision date	Dec 16, 2004
Days to decision	120 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pt. Mandiri Inti Buana**
Location	Medan, ID
Contact	P. SASITHARAN NAIR
510(k) history	4 submissions · 4 cleared · 2003-2005