FDA 510(k) Premarket Notification

K103770 SAME/VARIOUS DISTRIBUTORS/ WE MAY PRIVATE LABEL

CLEARED

Apr 21, 2011
115 days to decision

K103770 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k103770/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Dec 27, 2010
Decision date	Apr 21, 2011
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Syntex Healthcare Products Co., Ltd.**
Location	Xinji City, Hebei Province, CN
Contact	KATHY LIU
510(k) history	17 submissions · 17 cleared · 2002-2024

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k103770/ 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 May 26, 2026